Australian Government

Department of Health and Ageing

User Manual for the Export Electronic Lodgement (EEL) System

TGA THERAPEUTIC GOODS ADMINISTRATION

Online Services

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Introduction

Introduction

Welcome to the Therapeutic Goods Administration (TGA) eBusiness Services system. This system has been developed to provide the customers of TGA services with an easy and modern way of conducting business with TGA. From the Portal on the homepage all of the sub-systems within the Online Services system for the business units within TGA are able to be accessed.

Overview

This document is a user guide for the Export Electronic Lodgement system (EEL), a sub component of the eBusiness Services system. It provides an outline of the Export system and provides external customers with instructions for using the system.

Who Should Use This Manual

Any individual or organisation wishing to lodge an Export Only, Solely for Export or Export Certification (CPP) application to the TGA should use this document. This document will guide users through the functionality provided by the Export Electronic Lodgement system.

How to Use This Manual

This manual has been written for users of the Export Electronic Lodgement facility available from the TGA eBusiness Services web site. This document identifies each of the three main areas of export application (Export-Only (S26), Solely for Export (S26a) and Export Certificate) and treats each separately so as to allow the user to focus on the specific type of application as required. Other parts of this manual cover more generic system features such as site navigation and accessing Help.

Assumptions

It is assumed that users possess mouse skills and have a basic knowledge of the World Wide Web. Some Web terminology is explained for users in the 'Navigation' section of this manual.

Help

Help is available for all TGA eBusiness systems. For the various forms of help available refer to the Help Section in this document.

Overview of Export Only Medicines & Australian Register of Therapeutic Goods (ARTG)

Introduction

The Export Medicines system is a component of the larger TGA eBusiness Services system. The Export Medicines system is designed to provide a web-based interface between TGA's clients and the Export Medicine Unit of TGA. It provides the electronic forms necessary for submitting S26, S26a and for export certificates (CPP) applications. The Export system then offers support to TGA staff in the processing of these applications, and, once a listing application is successfully processed, supports the writing of these applications to the ARTG.

The ARTG holds records of all Therapeutic Goods that have been approved for supply in Australia and for export. The TGA eBusiness Services system (through Export Medicines and other business area components) controls this information through the level of access available to the user as detailed below.

Read access

- The Export system provides read only access for the records for which the client is either the sponsor or agent. From the ARTG View clients (sponsors or agents) can also create an ARTG certificate of that product based on the information found on that product record on the ARTG.

External access

The system also provides on-line access for TGA's clients and members of the public. Clients will have access to all their information while the public will have access to legally appropriate information via the Internet.

Benefits

The fundamental business objective of the Export Medicines system is to provide an efficient means of managing, tracking and reporting upon the processing and evaluation of client submissions.

Anticipated benefits that TGA clients will gain from the use of the Export Medicines system include the following:

- The quality of applications submitted will be enhanced by the instant validation of each application before submission.
- Time required for the creation of an application will decrease.
- Automatic notification via email if a product is successfully listed on the ARTG.
- Clients can track the progress of their applications on-line.

Getting Started

Introduction

The TGA eBusiness Services system is available through the Department of Health and Ageing web site. The TGA eBusiness Services web interface conforms to the Department of Health and Ageing web useability standards.

The TGA eBusiness Services Home Page

The TGA eBusiness Services Home Page is available at the following URL:

http://www.tgasime.health.gov.au/sime/home.nsf will need to have this entered later

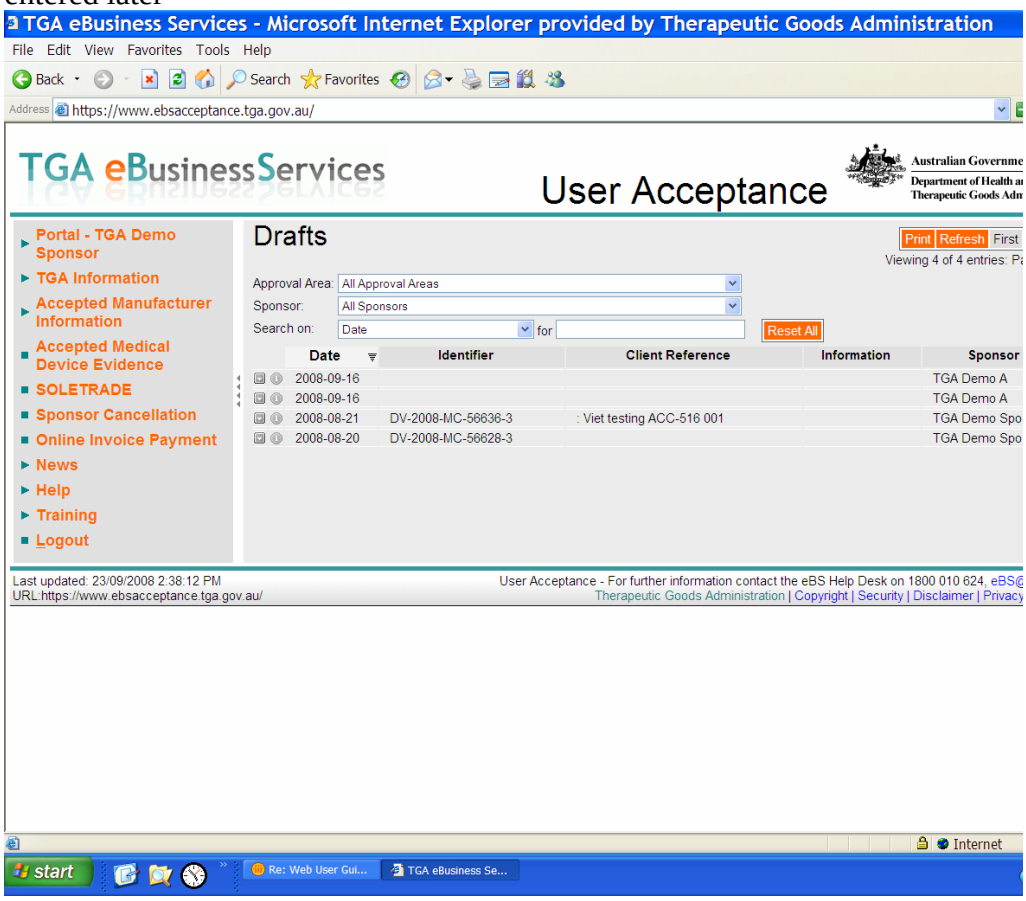


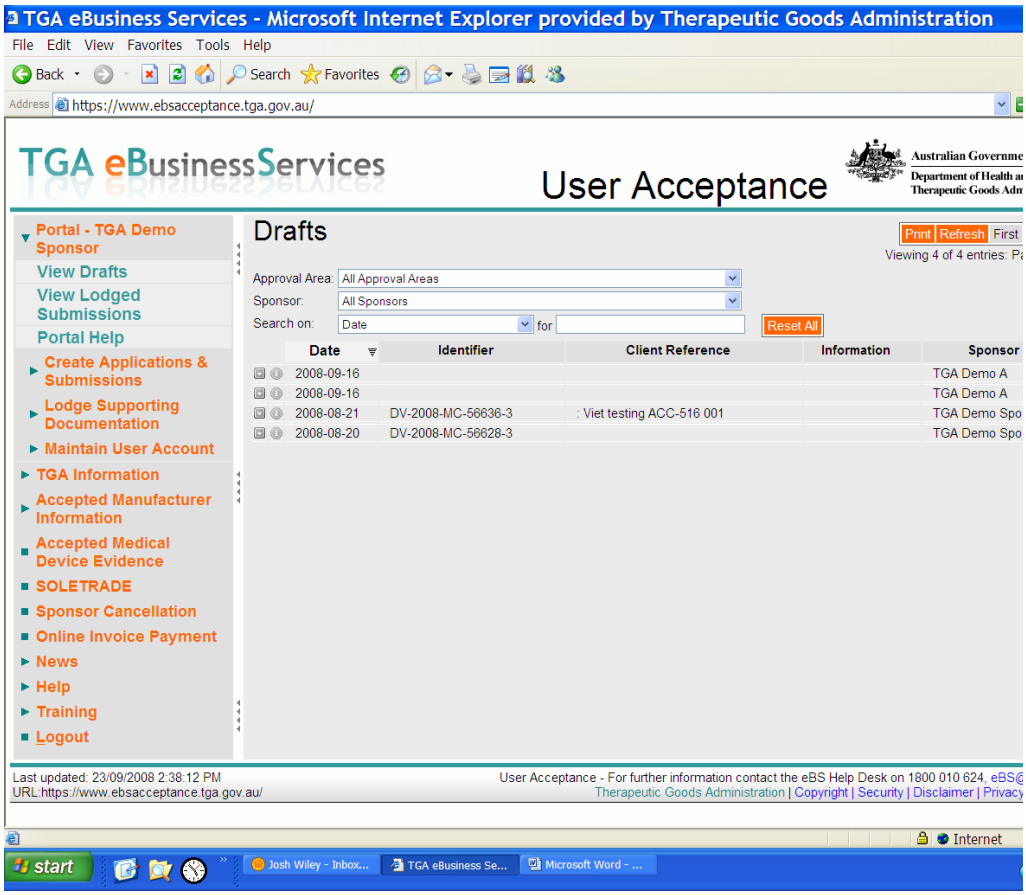
Figure 1. TGA eBusiness Services Home Page

The TGA eBusiness Services Home Page is publicly accessible. Security will be applied to most of the system beyond this point based upon the access that users have been granted. Only users who are registered as an “agent” or a “sponsor” will be able to access the Export Medicines applications.

Accessing Other Business Unit Systems

Access to the Export Electronic Lodgement system and TGA's other business unit systems is via the TGA eBusiness Services Home Page.

1. Navigate to the Home Page *(at the URL above)*
2. Click on the first twistie "Portal" to reveal the "View Drafts" link
3. As seen below in Figure 2. all drafts from all business unit systems are now accessible.



4. The Drafts page will display all current application drafts from all the business systems. To identify the drafts from one business area only use the dropdown list at the end of the "Approval Area" field and select the appropriate business area eg Export Only
If an agent with multiple clients, to search the drafts view for a specific client, use the filter beside the "Sponsor" field.

The eBusiness Services Web Environment

Navigation

Introduction

The TGA eBusiness Services system is designed to be easy to use. The system looks and works like many other prominent web-based applications, but it is useful to know and understand the functionality of the controls on the Online Services web pages, particularly those used for navigation.

The information regarding these navigation controls applies in the majority of circumstances. Instances where these navigation features will be nullified or changed in functionality will be advised at the appropriate point in the manual.

The eBS Button:
The eBS Home button is located in the top left of most pages in the system. It consists of the eBS logo. Use of this navigation control will return the user back to the TGA eBusiness Services home page. Although the logo will be present in the same location on every page in the system, the functionality of the button (to allow users to return to the TGA eBusiness home page) is only activated on pages where appropriate. On other pages, such as those that are part of application forms, this functionality is disabled to protect the integrity of information entered into the application interface.

The Previous and Next Buttons:
These buttons will appear on view screens, where lists of information are provided. For example the 'ARTG Records' view. They allow the user to navigate forwards or backwards through the list, and to move from one page to the next within a view.

The Search Button:
The search button is available when viewing lists of information. In the Export system this function is available in the 'ARTG Records' view.

The Home Button:
The home button is different from the SIME Home button. It will appear in application forms and at the top and bottom of a page. Clicking on this button will return the user to the Export home page.

The Validate Button:
This button is only available from all the application forms. This button allows a user to validate the information that they have supplied in an application prior to submission. If a particular mandatory field in the application has not been completed, or if a particular combination of information supplied creates a breech of TGA Export business rules, the application will fail validation. If an application does fail validation, detailed messages informing the user of the problem will be displayed near the top of the form. An application can not be submitted until it has passed validation.

The Submit Button:
This button allows the user to submit an application to the TGA. It is only available from the Make Submission screens. An application must be successfully validated before it can be submitted.

The Save Button:
This button will save the changes to the edited document, without closing it.

The Save & Close Button:
The Save & Close button will save and close the current document. You will return to the main view.

The Close Button:
This button closes the current document without saving the changes. You will be returned to the main view.

Sorting:
The ability to sort information is provided in the Drafts view within (EEL), allowing for users to find specific information more quickly. In the Drafts view for example, users are able to sort by the date an application was created. Clicking on the triangle icon at the top and to the right of the Date column heading will cause the view to be ordered by the column either in ascending or descending order of its contents.

Help

Introduction

All TGA Online Service systems provide users with an on-line Help facility. Help is available through the Help button found in the top right corner of each page within the application forms.

Accessing Help

Help is available on every screen within the EEL application forms. By clicking on the Help button, a Help window will open to display context sensitive information relating to the page within an application or an application type itself.

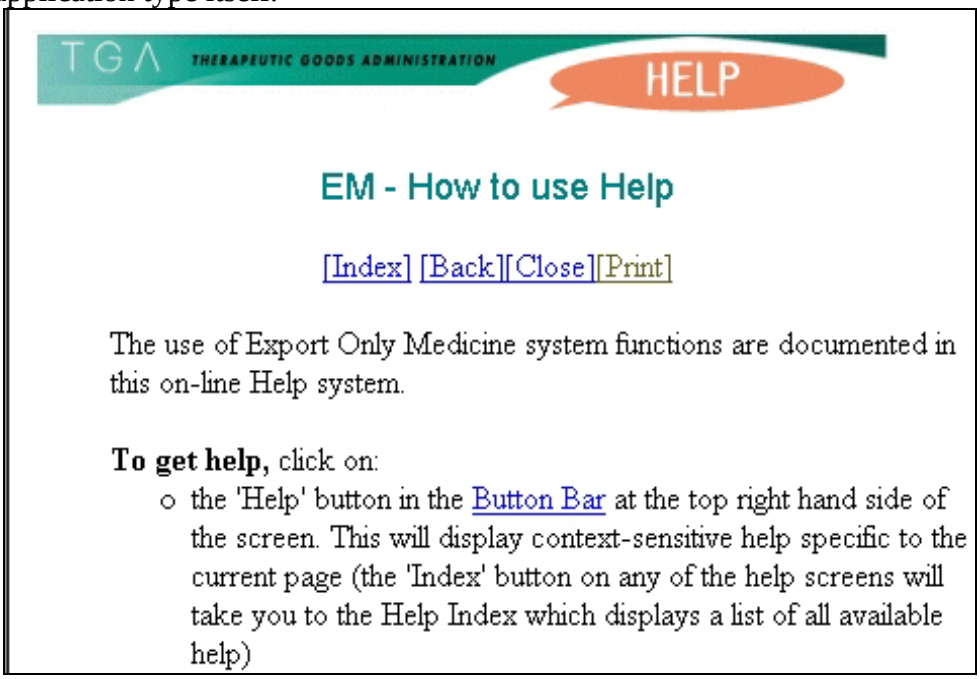

TGA
THERAPEUTIC GOODS ADMINISTRATION
HELP
EM - How to use Help
[Index] [Back][Close][Print]
The use of Export Only Medicine system functions are documented in this on-line Help system.
To get help, click on:
the 'Help' button in the Button Bar at the top right hand side of the screen. This will display context-sensitive help specific to the current page (the 'Index' button on any of the help screens will take you to the Help Index which displays a list of all available help)

Figure 3. An Example of a Help Page within the Export Medicines system

Help Conventions:

Throughout the on-line help system, certain actions and objects are indicated in the following ways:

- Buttons commands: The name of the button is placed in single quotes (‘ ‘). For example, click on **'OK'**, means the user clicks once on the button labelled OK.
- Keyboard commands: Key names are placed in greater/less than symbols. For example, press **<CTRL>,** means press the control (CTRL) key on your keyboard.
- Important messages and notes are written in italics. For example:

  ***Note**: These notes should always be read!*

Help Desk

If at any time you are experiencing problems using Export Medicine system or need further assistance, please contact the **Export Help Desk** on:

- E-mail: ebs@tga.gov.au
  Please include the word **EXPORT** in the subject line of the E-mail.
- Phone: 1800 092 788

The Export Help Desk operates Monday to Friday between the hours of 9:00–12:00am and 2:00–5:00pm EST.

If you require assistance gaining access to the TGA Online Services, please contact the **TGA Online Services Help Desk**:

- E-mail: ebs@tga.gov.au
- Phone: 1800 010 624

The Online Services Help Desk operates Monday to Friday between the hours of 8:30am – 5:00pm EST.

Export Applications

Mandatory and Conditionally Mandatory Fields

In all of the application forms of the Export Only system, there are certain information fields that are mandatory, and others that are conditionally mandatory.

The mandatory fields are prefixed with a red coloured star, and are always required otherwise the application can not be validated. Failure to supply information for a mandatory field prior to validation will result in a validation failure message indicating the field that is missing information.

Conditionally mandatory fields, indicated by a prefixed grey star, may become mandatory for validation purposes based upon information supplied in other fields - of the application. For example, in solely for export applications the use of particular ingredients in a product may be cause for limiting the total volume of the product container. Hence the container volume field would become mandatory, so the total volume of the container could be assessed as part of validating the application. If circumstances dictate that a conditionally mandatory field is required to be completed, and the field is not completed prior to validation, a validation failure message will indicate that the information is necessary. Similarly, in S26 Export Only applications, once a shelf life has been nominated, the fields “Shelf life temperature” and “Storage conditions” require entering also.

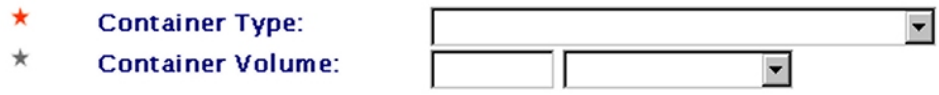


Figure 4. Examples of the Mandatory and Conditional Mandatory stars

NB: If not printing on a coloured printer the ‘Container Type’ above is a red star (mandatory field), the ‘Container Volume’ is a grey star (conditionally mandatory).

S26 – Export-Only Applications

Overview of an Export-Only General Listing Application

An Export-Only General Listing application is used for all medicine products other than Composite Packs and Change Multiple Current Listings. General Listing applications differ from Composite Pack applications only in that they have a single preparation in the same container where as Composite Pack applications have multiple preparations.

Creating an Export-Only General Listing Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link, under the Portal select the 'S.26 – Export Only' link.

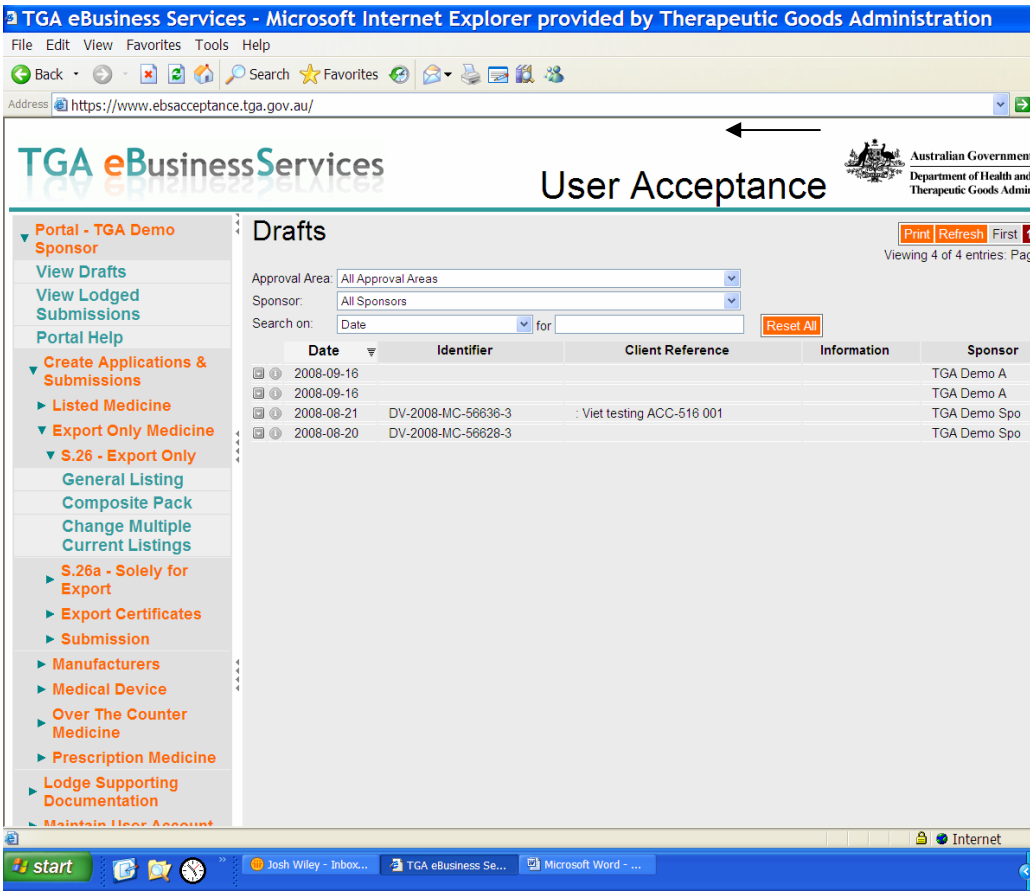


Figure 5. Export Medicines Home Page

2. The 'Export Only (S26) application types will be displayed. Select the 'General Listing' link.
3. The 'Export Only General Application' form will be displayed in edit mode, ready for information to be entered (see figure 6 below).
4. Complete the application using the information in the following table

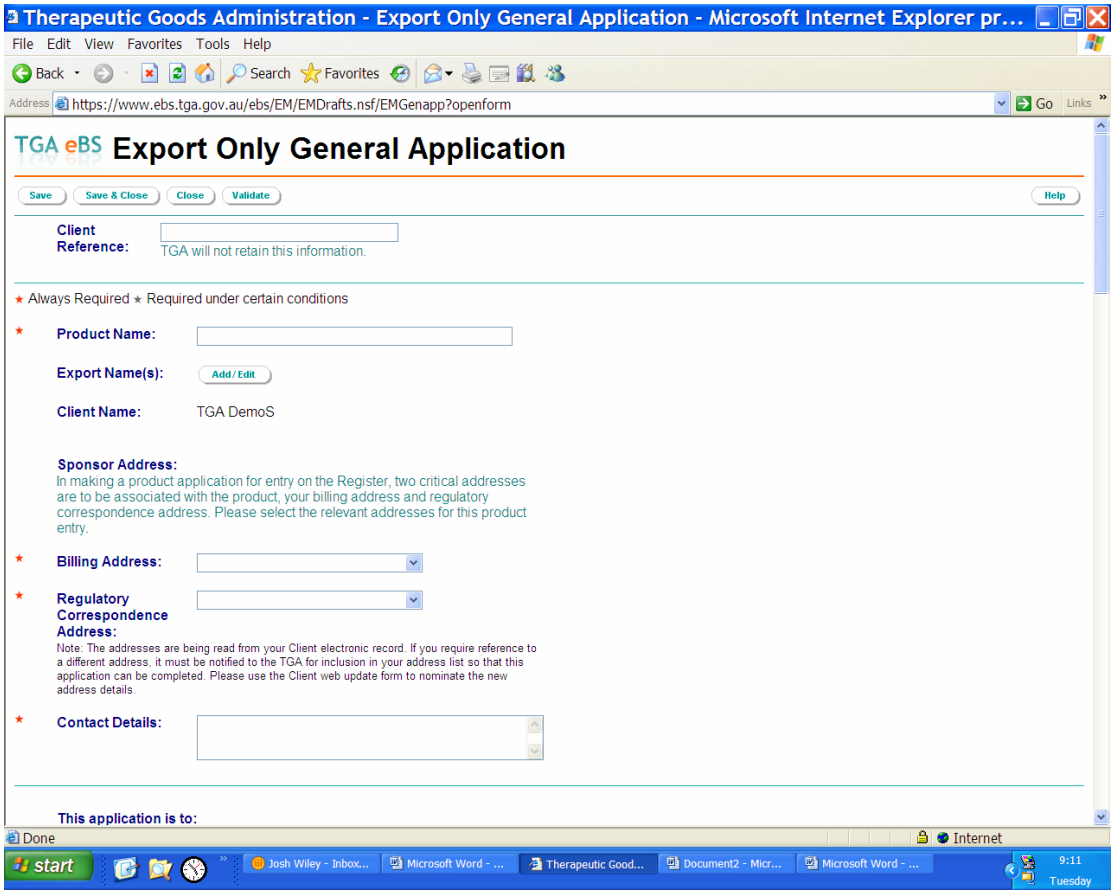

Therapeutic Goods Administration - Export Only General Application - Microsoft Internet Explorer pr...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/EMGenapp?openform
Go Links
TGA eBS Export Only General Application
Save
Save & Close
Close
Validate
Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Contact Details:
This application is to:
Done
Internet
start
Josh Wiley - Inbox...
Microsoft Word - ...
Therapeutic Good...
Document2 - Micr...
Microsoft Word - ...
9:11
Tuesday

Figure 6. Export Only General Application Form

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added. ‘Save and Close’ the subform.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Billing Address	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Correspondence Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Contact Details	This field is Mandatory. The name and telephone number of the person who is to be contact for any queries relating to this application are preferred here.

This application is to: change a current listing / create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
Change Description:	This field only becomes available if selecting 'Change a Current Listing' to the question above. To nominate the type of change being made to an existing listing, select from the drop down list and click on the 'Add' button.
Submission Cost:	Displays the submission cost when the draft application has been entered and validated.
Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.
Validation Report:	Displays a report of an attempt at validation of the draft application. Messages displayed will indicate the source of any application errors. These errors must be fixed to proceed with further validation attempts.
Formulation Details	
Dosage Form:	This field is mandatory. Select the dosage form for the formulation from the drop down list.
Route of Administration:	This field is mandatory. Single click the 'Add' button to display the route of administration table. Select the appropriate route/s of administration by clicking on them one at a time and then clicking OK. Multiple routes of administration can be added. Select the 'Save & Close' button to return to the application form.
Container Type:	This field is mandatory. Select the container type for the formulation from the drop-down list.
Container Volume/ Container Material/ Container Closure	These fields are conditionally mandatory. Enter the formulation container volume and select the container volume units from the drop down list. Repeat the process (selecting from the appropriate drop down lists) to populate other container related fields.

Visual identification of dosage form:	This field is mandatory. Enter a text description of the visual identification of dosage form.
Is this component supplied sterile?	This field is mandatory. Select ‘Yes’ or ‘No’. If ‘Yes’ is selected then the Sterility Description field that appears, must be completed.
Sterility Description:	This field is conditionally mandatory. If selecting ‘Yes’ to the question above, this field will become available. Select the method of sterility from the drop-down list.
Ingredient:	This field is mandatory. Single click the ‘Add’ button to add an ingredient to the application. Multiple ingredients can be added. For details on the Ingredient Subform refer to Page 43
Manufacturer(s):	This field is mandatory. Single click the ‘Add’ button to add a manufacturer to the application. Multiple manufacturers can be added. For details on the Manufacturer Subform refer to Page 47
Product Details	
Pack Sizes:	This field is conditionally mandatory. Single click the "Add/Edit" button to add or edit a pack size for the application. Multiple pack sizes can be added. ‘Save & Close’ to update the application.
Will product comply with specific and general standards applicable to product under Chapter 3, Part 3/1 Standards of Therapeutic Goods Act 1989 during the entire shelf life of the product?	The system default response has been set on 'No'. Selecting 'Yes' or 'N/A' will remove the following text field for non-compliance justification.
Justification for non-compliance with specific and general standards applicable to product under Chapter 3, Part 1/3 Standards of the Therapeutic Goods Act 1989:	An entry in this field is only required if the previous field is answered 'No'. Otherwise this field will be hidden.
Has this product been cancelled, recalled or rejected for registration or listing on ARTG for supply in Australia?	Select 'Yes' or 'No'. The system default response has been set on ‘No’ Selecting ‘Yes’ will result in the following field becoming available.
Details of prior cancellation, recall etc:	This field is hidden if ‘No’ is selected as above. Otherwise details of previous cancellation or recall in are required to be entered in the text field.
Has this product been granted marketing approval for supply in the importing country?	Select 'Yes' or 'No'. The system default response is ‘No’. Selecting ‘Yes’ will result in the following field becoming available.
Details of Approval:	This field is hidden if ‘No’ is selected for the question above, otherwise provide details of the marketing approval in the text field. Only one country’s approval details are required.

Have you launched an application for grant of marketing approval in the importing country?	This question is only available if 'No' is selected to the question opposite. The system default response is 'No'. Selecting 'Yes' will result in the following field becoming available.
Please comment on present status of your application:	This field is hidden if 'No' is selected for the question above. If 'Yes' is selected for the above field, provide details of the status of the marketing application in the text field.
To be exported as fully finished product?	Select 'Finished Product' or 'Bulk Product'
The shelf life of this product under the recommended storage condition as stated on the label is:	Select the appropriate period of time from the drop-down list. Similarly, to nominate shelf life temperature and storage conditions, select the desired options from the appropriate drop down lists.
Proposed Therapeutic Indications:	This field is non-mandatory. Text can be provided for the proposed therapeutic indications to be displayed on the label.
Electronic Supporting Attachment List	
Attachments:	This is conditionally mandatory depending on if the user has selected to 'Add' an electronic file. One or more electronic files can be attached to the application by clicking 'Add'. For example: Product label and Product specification. To '**Delete'** an electronic file select the 'Delete' link in the Attachment table, under the Action column.
Paper Supporting Document List	
Paper Supporting Document List:	This is conditionally mandatory depending on if the user has selected to 'Add' a paper supporting document type: Select the type of document.
Description:	Provide a free text description of the document.
Method of Submission:	Select the method via which the document has been (will be sent).
Date Sent:	Select the date on which the document was/will be sent. Complete the addition of a paper-supporting document by clicking 'Add' once all the details are completed. Note: The system default is today's date, however this can be updated.
To remove a paper supporting documents select the item number of the document from the drop down list and select 'Remove'	
Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to ‘Validating an Application’ on Page 74 for details.
6. ‘Save and Close’ the application. The application will now be available from the ‘View Drafts” option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of ‘Passed Validation’ it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76

The Composite Pack Application

A Composite Pack application is used for composite packs as defined in Therapeutic Goods Act 1989 Subsection 7B(2). Composite Pack applications differ from General Listing applications only in that they have multiple preparations in the same container where as General Listing applications have a single preparation.

Creating a Composite Pack Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link under the Portal select the 'S.26 – Export Only' link.
2. The 'Export Only (S26) application types will be displayed. Select the 'Composite Pack' link.
3. The 'Export Only Composite Pack Application' form will be displayed in edit mode, ready for information to be entered (see the Figure below).

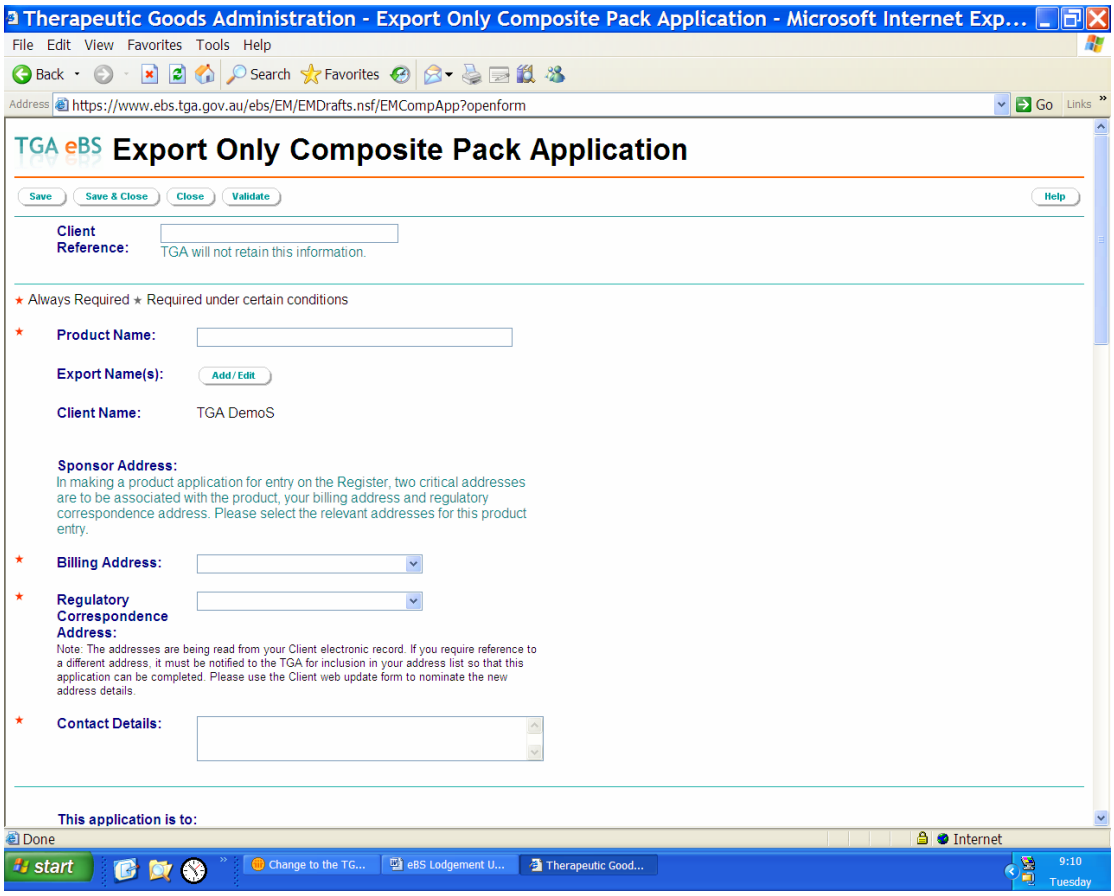

Therapeutic Goods Administration - Export Only Composite Pack Application - Microsoft Internet Exp...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/EMCompApp?openform
Go Links
TGA eBS Export Only Composite Pack Application
Save
Save & Close
Close
Validate
Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Contact Details:
This application is to:
Done
Internet
start
Change to the TG...
eBS Lodgement U...
Therapeutic Good...
9:10
Tuesday

Figure 7. Export Only Composite Pack Application Form

4. Complete the Application by entering information into the following fields:

Field	Description
Client Reference	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added by adding <Enter> at the end of each name. 'Save and Close' the subform.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Contact Details:	This field is Mandatory. The name and telephone number of the person who is to be contact for any queries relating to this application are preferred here.
This application is to: change a current listing/create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
Change Description:	This field only becomes available if selecting 'Change a Current Listing' to the question above. To nominate the type of change being made to an existing listing, select from the drop down list and click on the 'Add' button.
Submission Cost:	Displays the submission cost when the draft application has been entered and validated.

Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.

Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.
Validation Report:	Displays a report of an attempt at validation of the draft application. Messages displayed will indicate the source of any application errors. These errors must be fixed to proceed with further validation attempts.
Formulation Details:	Single click the 'Add' button to add a formulation to the application. Multiple formulations can be added. For details on the Formulation Subform, refer to Page 49
Manufacturer(s):	This field is mandatory. Single click the 'Add' button to add a manufacturer to the application. Multiple manufacturers can be added. For details on the Manufacturer's Subform, refer to Page 47

Product Details	
Does this Composite Pack include a medical device registered on the ARTG?	Select 'Yes' or 'No'. System default response is 'No'. If 'Yes' is chosen, the form will refresh, providing a free text field for device details.
Will product comply with specific and general standards applicable to product under Chapter 3, Part 3/1 Standards of Therapeutic Goods Act 1989 during the entire shelf life of the product?	The system default response has been set on 'No'. Selecting 'Yes' or 'N/A' will remove the following text field for non-compliance justification.
Justification for non-compliance with specific and general standards applicable to product under Chapter 3, Part 3/1 Standards of Therapeutic Goods Act 1989:	If 'No' is selected for the above question then this is a mandatory field. Enter a text description of the justification for non-compliance.

Has this product been cancelled, recalled or rejected for registration or listing on ARTG for supply in Australia?	Select 'Yes' or 'No'. The system default response has been set on 'No' Selecting 'Yes' will result in the following field becoming available.
Details of prior cancellation, recall etc.	This field is hidden until Yes is selected for the question above. Provide details of previous cancellation or recall in the text field.
Has this product been granted marketing approval for supply in the importing country?	Select 'Yes' or 'No'. The system default response is 'No'. Selecting 'Yes' will result in the following field becoming available.
Details of approval:	This field is hidden if 'No' is selected for the question above, otherwise provide details of the marketing approval in the text field. Only one country's approval details are required.
Have you launched an application for grant of marketing approval in the importing country?	This question is only available if 'No' is selected to the question opposite. The system default response is 'No'. Selecting 'Yes' will result in the following field becoming available.
Please comment on the present status of your application:	This field is hidden until 'Yes' is selected for the question above. Provide details of the application in the text field provided.
To be exported as fully finished product?	Select 'Finished Product' or 'Bulk Product'
The shelf life of this product under the recommended storage condition as stated on the label is:	Select the appropriate period of time for the shelf life. Once a value is selected, select the appropriate option to display time. . Similarly, to nominate shelf life temperature and storage conditions, select the desired options from the appropriate drop down lists.
Proposed Therapeutic Indications:	This field is not mandatory. If desired, provide the text for the proposed therapeutic indications to be displayed on the new product record.

Electronic Supporting Attachment List	
Attachments:	This is conditionally mandatory depending on if the user has selected to 'Add' an electronic file. One or more electronic files can be attached to the application by clicking 'Add'. To '**Delete'** an electronic file select the 'Delete' link in the Attachment table, under the Action column.

Paper Supporting Document List	
Document Type:	Select the type of document from the drop-down list provided.
Description:	Provide a free text description of the document.
Method of Submission:	Select the method via which the document has been (will be sent).
Date Sent:	Select the date on which the document was/will be sent. Complete the addition of a paper-supporting document by clicking 'Add' once all the details are completed. Note: The system default is today's date, however this can be updated.
To remove a paper supporting document select the item number of the document from the drop down list and select 'Remove'	
Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
6. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76

The Change to Multiple Current Listings Application

A Change Multiple Listing application is used to make specific changes to multiple existing ARTG listings. The details that can be changed include certain parts of the product name and any common manufacturing steps. Additionally new common manufacturers and pack sizes can be added to all selected ARTG listings.

Creating a Change to Multiple-Current Listings

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link under the Portal select the 'S.26 – Export Only' link.
2. The 'Export Only (S26) application types will be displayed. Select the 'Change multiple current listings' link. The 'Variation Change Multiple Listings Application' form will be displayed in edit mode, ready for information to be entered (see figure 8 below).
3. Complete the Application by entering information into the following fields

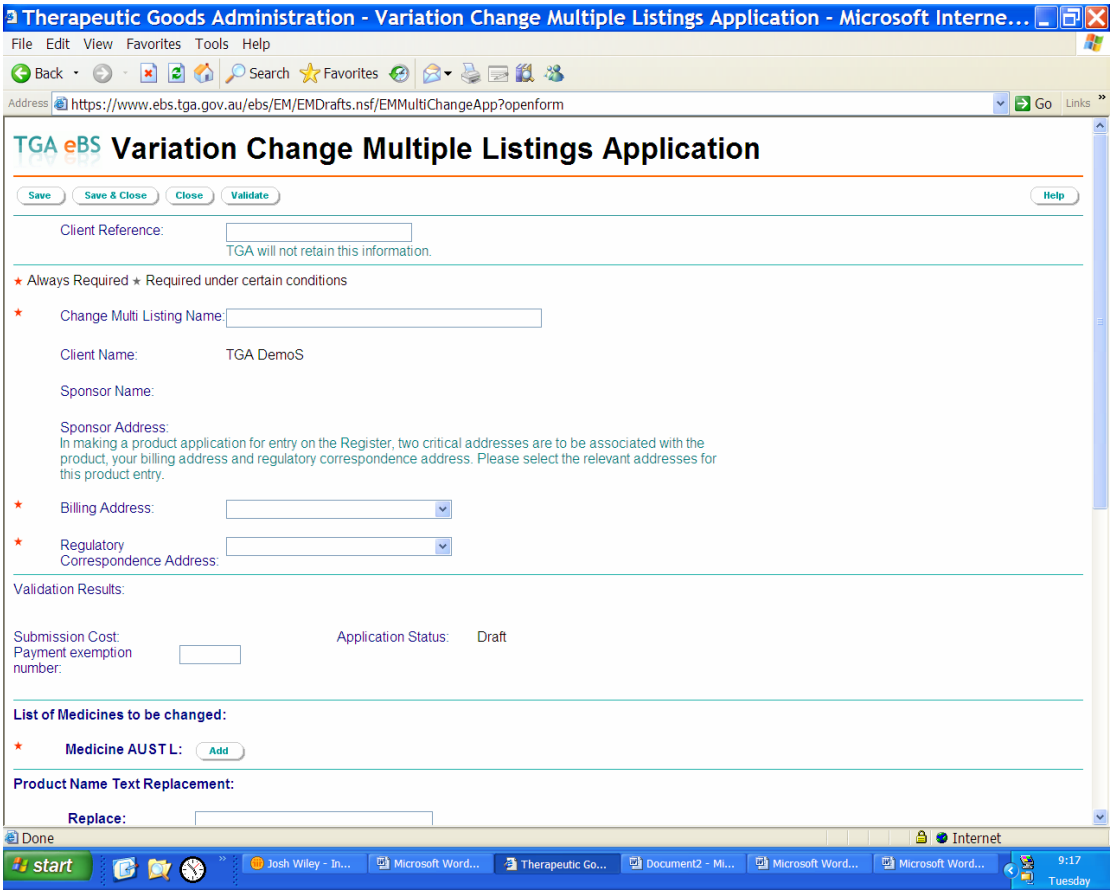


Figure 8. Export Only Multiple Change Listing Form

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Change Multi Listing Name:	This field is mandatory. Enter the name of the Change Multiple Listing draft. This name will be used to identify the set of current listings that will have the changes made to them. However, it will not be written to the ARTG.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Sponsor Name:	This field is Mandatory. If this form is being used by an Agent, select appropriate sponsor name from the list.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.

Validation Report:	Displays a report of an attempt at validation of the draft application. Messages displayed will indicate the source of any application errors. These errors must be fixed to proceed with further validation attempts.
Submission cost:	Displays the submission cost when the draft application has been entered and validated.
Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated. In the case of multiple listing, application type is always Variation. Note: This field only appears when the application status is 'Passed Validation'.
List of Medicines to be changed:	
Medicine AUST L:	This field is Mandatory. Single click the 'Add' button to add an existing medicine AUST L to the application. Search for the AUST L and Save and Close the subform. Multiple medicines can be added. Medicines selected will be displayed in a table on the application form.
Product Name Text Replacement:	Replace: Enter the part of the product name text to be replaced. This text must be common to the names of all the products selected. With: Enter the new text to use in the product name.

Common Manufacturing Steps:	
Remove Steps:	Only manufacturing steps that are common to all the selected medicines will be displayed in the table. **Delete** any common manufacturing steps listed in the table as required by clicking on the tick-box next to the step. Single click the 'Add' button to add common manufacturing steps to all of the selected medicines.
New Manufacturers:	
Manufacturers:	Single click the 'Add' button to add common manufacturers to all of the selected medicines. Refer to Page 47 for details on the Manufacturers subform.
Common Pack Sizes:	
Remove Pack Sizes	Only pack sizes that are common to all the selected medicines will be displayed in the table. Delete any common pack sizes listed in the table as required. Single click the 'Add' button to add common pack sizes to all of the selected medicines.
Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

4. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
5. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
6. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76

Changing a Single Current Listing (Variation / Grouping)

This option allows users to make changes to a single current listing on the ARTG. This is achieved by opening a General Listing Application form or a Composite Pack form from the 'Export Only Medicines' underneath the 'Create Applications & Submissions' link and selecting the 'S.26 – Export Only' link.
The 'Export Only (S26) application types will be displayed and once the appropriate application form has been selected and opened, selecting the 'Change a current listing' button as seen below:

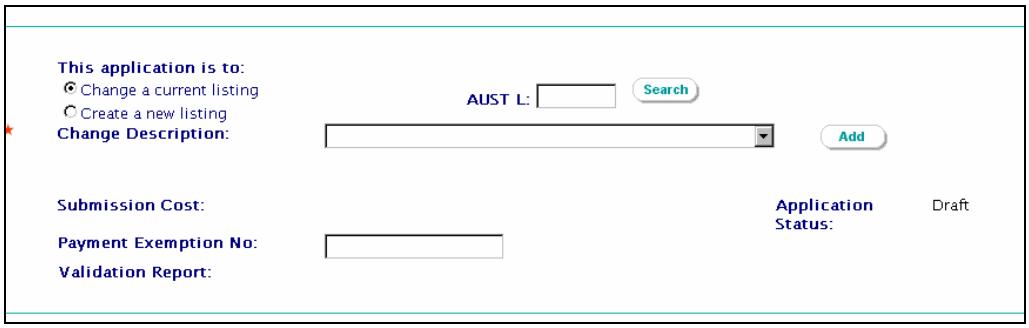


Figure 9. Export – Fields available on the Application form for changing a current listing

Creating a change to a single current listing through General Listings Application or Composite Pack

When this option is selected, the AUST L field will be displayed. Enter the AUST L number of the product in this field and click on the 'Search" button. The application will now be populated with the existing ARTG information for the product selected.
A Change Description can now be selected from the drop down list in the Change Description field. Once selected click on the 'Add' button.
The desired changes to the existing record can now be made within the application, provided that they are changes that can be made either as a Variation or a Grouping.
The application must be Saved and Validated successfully. It can then be submitted to the TGA for processing, refer to the 'Making a Submission' section in this manual.

Note: Making the changes to the application will not automatically update the information on the ARTG. The application must be submitted to the TGA for processing and approval before the ARTG record will be updated.

S26a – Solely for Export Applications

The Solely for Export - General Listing Application

Solely for Export applications are reviewed under Section 26a of the Therapeutic Goods Act 1989. A General Listing application is used for all listed medicine products other than Composite Packs, Medicine Kits and products prepared from code stock. General Listing applications differ from Composite Pack applications only in that they have a single preparation in the same container where as Composite Pack applications have multiple preparations.

Creating a Solely for Export General Listing Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link unde the Portal select the 'S.26a – Solely for Export' link .
2. The 'S.26a Solely for Export' application types will be displayed. Select the 'General Application' link.
3. The 'S.26a Solely for Export General Application' form will be displayed in edit mode, ready for information to be entered (see Figure 10 below).
4. . Complete the Application by entering information into the following fields

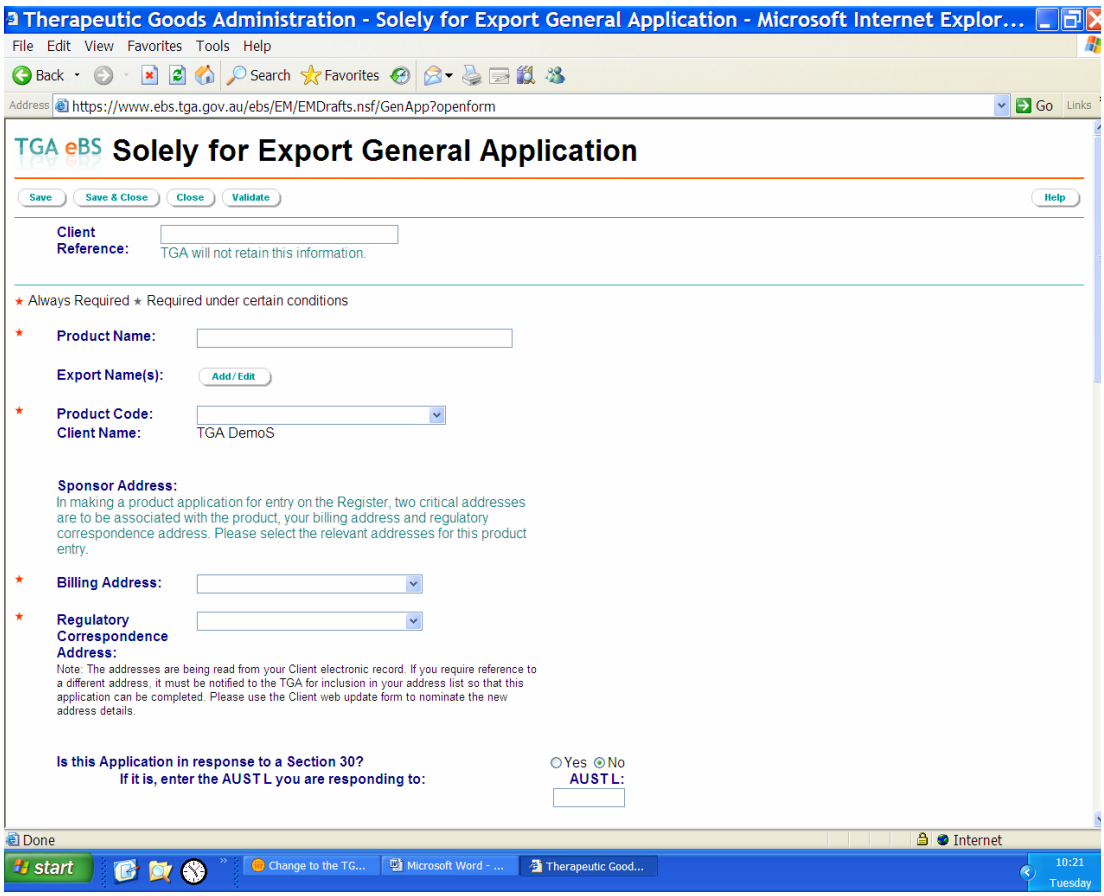

Therapeutic Goods Administration - Solely for Export General Application - Microsoft Internet Explor...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/GenApp?openform
Go Links
TGA eBS Solely for Export General Application
Save
Save & Close
Close
Validate
Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Product Code:
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Is this Application in response to a Section 30?
If it is, enter the AUST L you are responding to:
Yes No
AUST L:
Done
Internet
start
Change to the TG...
Microsoft Word - ...
Therapeutic Good...
10:21
Tuesday

Figure 10. Solely for Export General Application Form

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.

Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added by pressing 'Enter' and the end of each name. Save and Close subform.
Product Type:	This field is mandatory. Select the product type from the drop down list.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Is this Application in response to a Section 30?	The system default is 'No'. Select "Yes" if this application is being submitted as a response to a Section 30 request. Enter the AUST L being responded to.
Can this product be used as a code stock?	The system default is 'No'. Select "Yes" if this application can be used as a code stock.

This application is to: change a current listing/create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
AUST L:	This field is hidden until 'Change a current listing' is selected to the question above. Enter an AUST L number from which to create a new draft copy. Single click the "Search" button, the application form will populate with the details of the AUST L record entered.
Submission Cost:	This field will be automatically populated once an application is validated. It displays the submission cost of the application.
Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). ***Note***: this field only appears when the Application status is valid.
Validation Report:	Displays a report of an attempt at validation of the draft application. Messages displayed will indicate the source of any application errors. These errors must be fixed to proceed with further validation attempts. Note: Validation rules for solely for export applications are the same as for listed medicines under ELF.

Formulation Details:	
Dosage Form:	This field is mandatory. Select the dosage form for the formulation from the drop down list.
Route of Administration:	This field is mandatory. Single click the 'Add' button to display the route of administration table. Select the appropriate route/s of administration by clicking on them one at a time and then clicking OK. Multiple routes of administration can be added. Select the 'Save & Close' button to return to the application form.
Container Type:	This field is mandatory. Select the container type for the formulation from the Drop-down list.
Container Volume:	This field is conditionally mandatory. The use of particular ingredients in the formulation may require the declaration of the container volume. Enter the formulation container volume and select the container volume units from the drop down list.

Container Closure: Container Condition	These fields are conditionally mandatory. The inclusion of particular ingredients may require the declaration of the container closure type, particularly if the ingredient can not be supplied without a child resistant closure. Select the container closure for the formulation from the drop down list. Similarly, select the container condition option from the appropriate drop down list.
Maximum Single Dose:	This field is conditionally mandatory. The inclusion of particular ingredients may require the declaration of a maximum single dose. Enter the formulation's recommended maximum single dosage and select the units from the drop down list
Maximum Daily Dose:	This field is conditionally mandatory. The inclusion of particular ingredients may require the declaration of a maximum daily dose. Enter the formulation's recommended maximum daily dosage and select the units form the drop down list
Minimum Weight of Divided Dosage Form:	This field is conditionally mandatory. The inclusion of particular ingredients may require the declaration of the maximum weight of the divided dosage. Enter the formulation's recommended maximum single dosage and select the units from the drop down list
Ingredient:	This field is mandatory. Single click the 'Add' button to add an ingredient to the formulation. Multiple ingredients can be added. For details on the Ingredient subform, refer to Page 43
Manufacturer(s):	This field is mandatory. Single click the 'Add' button to add a manufacturer to the application. Multiple manufacturers can be added. For details on the Manufacturers subform, refer to Page 47.

Product Details:	
Indications:	This field is mandatory. Single click the 'Add' button to add an indication to the application. Multiple indications can be added. For details on the Indications subform, refer to Page 56
Warning	This field is conditionally mandatory. Single click the 'Add' button to add a warning to the application. Multiple warnings can be added. For details on the Warnings subform, refer to Page 57.

Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to ‘Validating an Application’ on Page 74 for details.
6. ‘Save and Close’ the application. The application will now be available from the ‘View Drafts” option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of ‘Passed Validation’ it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

The Solely for Export – Medicine Application prepared from a Code Stock

A Code Stock application is used for products prepared from code stock. This type of application is based on an existing ARTG listing which has been flagged as being available for use as a code stock.

Creating a Solely for Export Medicine Application prepared from a Code Stock

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link under the Portal select the 'S.26a – Solely for Export' link .
2. The 'S.26a Solely for Export' application types will be displayed. Select the 'Solely for Export Medicine Prepared from a code stock' application link.
3. The 'Solely for Export Medicine Prepared from a code stock' application form will be displayed in edit mode, ready for information to be entered (see Figure 11 below).
4. . Complete the Application by entering information into the following fields

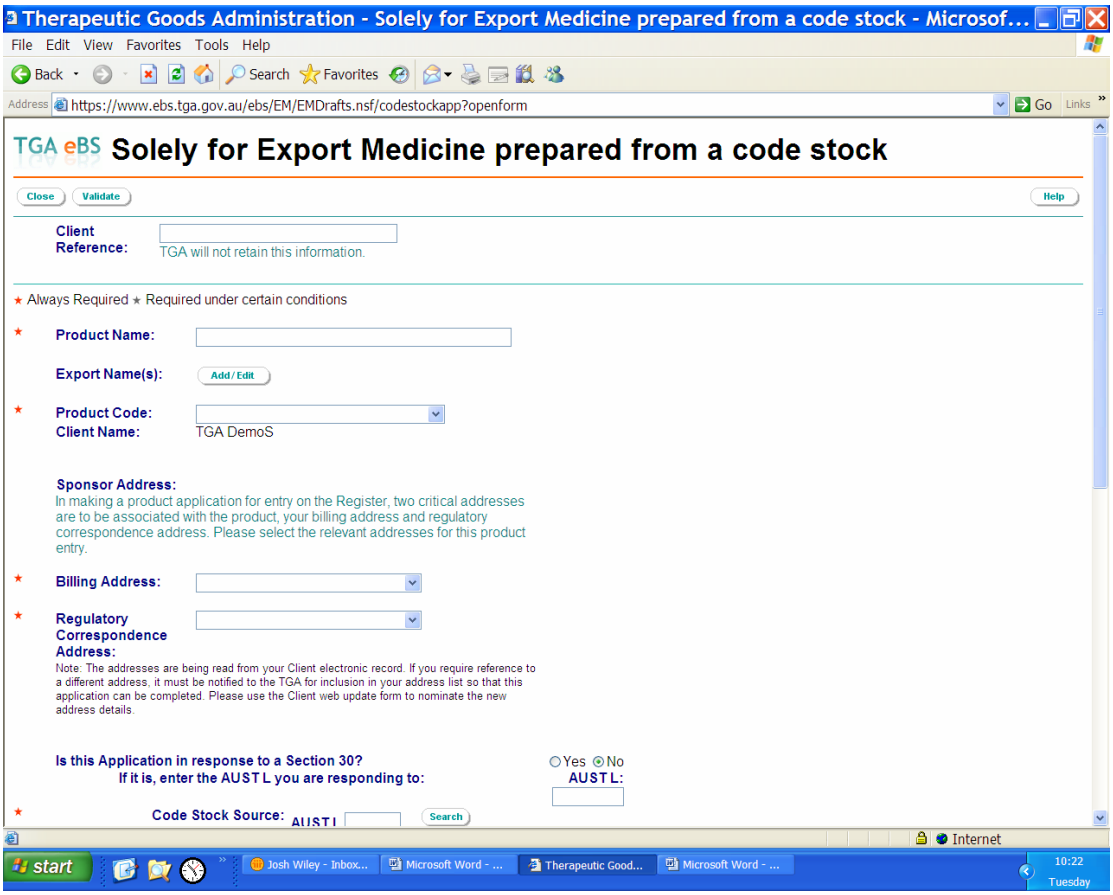

Therapeutic Goods Administration - Solely for Export Medicine prepared from a code stock - Microsof...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/codestockapp?openform
Go Links
TGA eBS Solely for Export Medicine prepared from a code stock
Close Validate Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Product Code:
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Is this Application in response to a Section 30?
Yes No
If it is, enter the AUST L you are responding to:
AUST L:
Code Stock Source: AUST
Search
Internet
start
Josh Wiley - Inbox...
Microsoft Word - ...
Therapeutic Good...
Microsoft Word - ...
10:22
Tuesday

Figure 11. Solely for Export Medicine prepared from a code stock application form.

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added by adding 'Enter' behind each name. Save and Close the subform.
Product Type:	This field is mandatory. Select the product type from the drop down list.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Is this Application in response to a Section 30?	The system default is 'No'. Select "Yes" if this application is being submitted as a response to a Section 30 request. Enter the AUST L being responded to.
Code Stock Source?	This field is Mandatory. Enter an AUST L number of an existing ARTG entry, which can be used as a code stock from which to create a new draft copy. Single click the "Search" button to create the new draft application based on the entered AUST L number.

This application is to: • Change a current listing or • Create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
AUST L:	This field is hidden until 'Change a current listing' is selected to the question above. Enter an AUST L number from which to create a new draft copy. Single click the "Search" button, the application form will populate with the details of the AUST L record entered.
Submission Cost:	This field will be automatically populated once an application is validated. It displays the submission cost of the application.
Application Status:	This field is populated by the system depending on the

	current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.
Validation Report:	On Validating the application the system displays a validation report. Messages displayed will indicate any errors will the application. These errors must be fixed before the application can be submitted to the TGA.

Formulation details:	When an application uses an existing ARTG code stock listing as a base for the formulation details, the formulation details are added to the code stock new application and are only available in read mode.
Manufacturer(s):	This field is mandatory. Single click the 'Add' button to add a manufacturer to the application. Multiple manufacturers can be added. For details on the Manufacturers subform, refer to Page 47.

Indications:	This field is mandatory. Single click the 'Add' button to add an indication to the application. Multiple indications can be added. For details on the Indications subform, refer to Page 56
Warning	This field is conditionally mandatory. Single click the 'Add' button to add a warning to the application. Multiple warnings can be added. For details on the Warnings subform, refer to Page 57.

Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
6. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

The Solely for Export Medicine Kit application

A Medicine Kit Listing application is used when collections of existing medicines are to be sold together as a purpose built kit.

Creating a Solely for Export Medicine Kit application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link under the Portal select the 'S.26a – Solely for Export' link .
2. The 'S.26a Solely for Export' application types will be displayed. Select the 'Solely for Export Medicine Prepared from a code stock' application link.
3. The 'Solely for Export Medicine Kit Listing Application' form will be displayed in edit mode, ready for information to be entered (see Figure 12 below).

.4. Complete the Application by entering information into the following fields

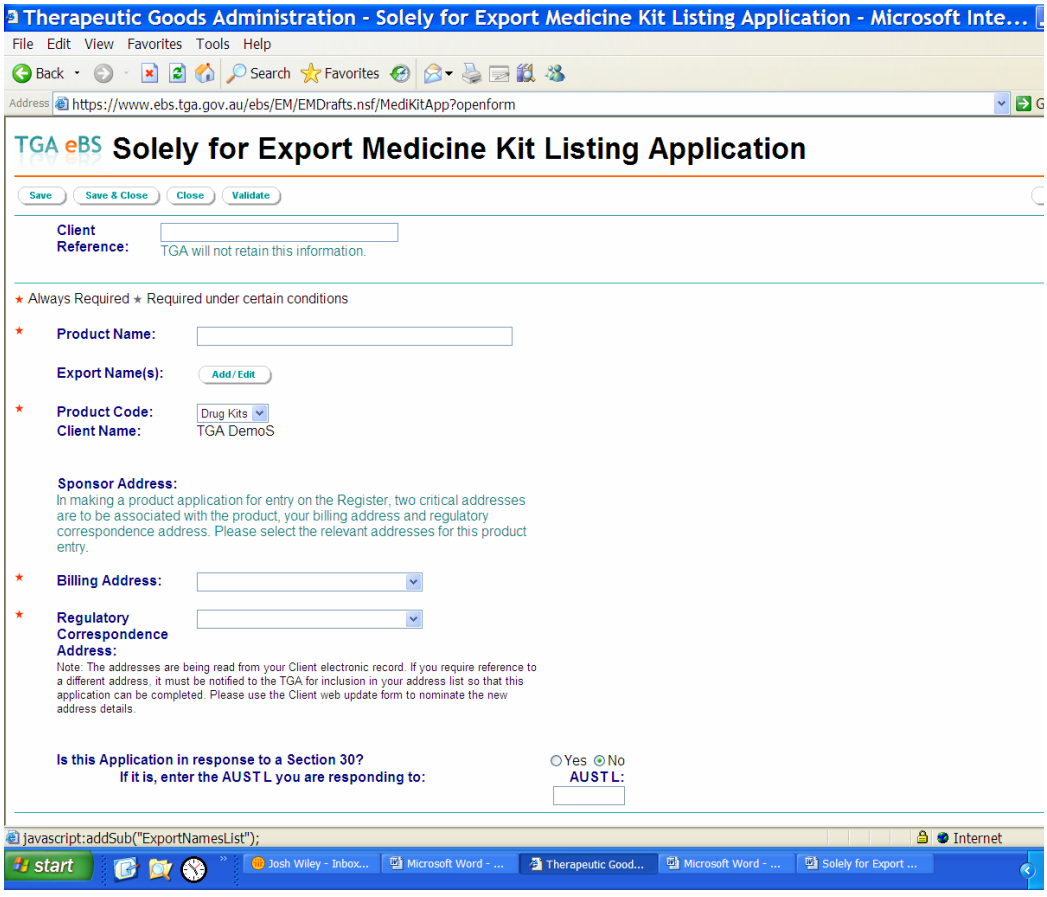

Therapeutic Goods Administration - Solely for Export Medicine Kit Listing Application - Microsoft Inte...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/MediKitApp?openform
TGA eBS Solely for Export Medicine Kit Listing Application
Save Save & Close Close Validate
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Product Code:
Drug Kits
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Is this Application in response to a Section 30?
If it is, enter the AUST L you are responding to:
Yes No
AUST L:
javascript:addSub("ExportNamesList");
Internet
start
Josh Wiley - Inbox...
Microsoft Word - ...
Therapeutic Good...
Microsoft Word - ...
Solely for Export ...

Figure 12. Solely for Export Medicine Kit Listing Application Form

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Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added.
Product Type:	This field is mandatory. Select the product type from the drop down list.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export system.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Is this Application in response to a Section 30?	The system default is 'No'. Select "Yes" if this application is being submitted as a response to a Section 30 request. Enter the AUST L being responded to.

This application is to: change a current listing/create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
AUST L:	This field is hidden until 'Change a current listing' is selected to the question above. Enter an AUST L number from which to create a new draft copy. Single click the "Search" button, the application form will populate with the details of the AUST L record entered.
Submission Cost:	This field will be automatically populated once an application is validated. It displays the submission cost of the application.
Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.

Validation Report:	On Validating the application the system displays a validation report. Messages displayed will indicate any errors will the application. These errors must be fixed before the application can be submitted to the TGA.

Listed/Registered Medicine:	This field is mandatory. Single click the 'Add' button to add a medicine to the application. Search for the AUST L/R and Save and Close the subform. Multiple medicines can be added be repeating the process.
Exempt Medicines:	Single click the 'Add' button to add an exempt medicine to the application. Enter the details, Save and Close the subform. Multiple exempt medicines can be added by repeating the process.
Manufacturer(s):	This field is mandatory. Single click the 'Add' button to add a manufacturer to the application. Multiple manufacturers can be added. Fore details on the Manufacturers subform, refer to Page 47.
Indications:	This field is mandatory. Single click the 'Add' button to add an indication to the application. Multiple indications can be added. For details on the Indications subform, refer to Page 56
Warning	This field is conditionally mandatory. Single click the 'Add' button to add a warning to the application. Multiple warnings can be added. For details on the Warnings subform, refer to Page 57.

Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
6. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

Creating a Composite Pack Application

A Composite Pack application is used for all listed medicine products other than General Listing (including variation and grouping), Medicine Kits and products prepared from code stock. Composite Pack applications differ from General Listing applications only in that they have multiple preparations in the same container where as General Listing applications have a single preparation.

How to create a Composite Pack Application

From the ‘Export Only Medicine’ link underneath the ‘Create Applications & Submissions’ link under the Portal select the ‘S.26a – Solely for Export’ link .

The ‘S.26a Solely for Export’ application types will be displayed. Select the ‘Solely for Export Composite Pack Application’ link.

The ‘Solely for Export Composite Pack Application’ form will be displayed in edit mode, ready for information to be entered (see Figure 13 below).

. Complete the Application by entering information into the following fields

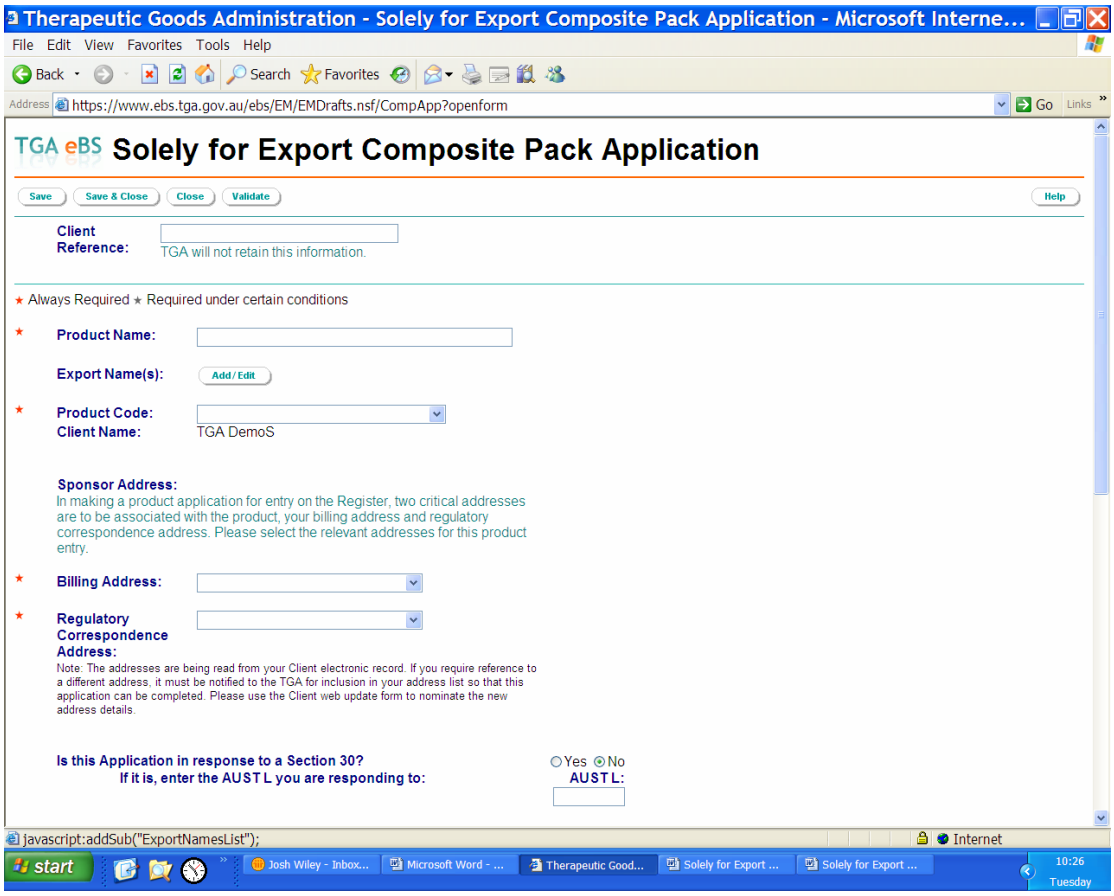

Therapeutic Goods Administration - Solely for Export Composite Pack Application - Microsoft Interne...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/CompApp?openform
Go Links
TGA eBS Solely for Export Composite Pack Application
Save
Save & Close
Close
Validate
Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Product Name:
Export Name(s):
Add / Edit
Product Code:
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being read from your Client electronic record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.
Is this Application in response to a Section 30?
If it is, enter the AUST L you are responding to:
Yes No
AUST L:
javascript:addSub("ExportNamesList");
Internet
start
Josh Wiley - Inbox...
Microsoft Word - ...
Therapeutic Good...
Solely for Export ...
Solely for Export ...
10:26
Tuesday

Figure 13. Solely for Export Composite Pack Application Form

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Product Name:	This field is mandatory. Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Export Names:	This field is not mandatory. Single click the "Add/Edit" button to add an export name to the application. Multiple export names can be added by clicking 'Enter' and the end of each name.
Product type:	This field is mandatory. Select the product type from the drop down list.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Is this Application in response to a Section 30?	The system default is 'No'. Select "Yes" if this application is being submitted as a response to a Section 30 request. Enter the AUST L being responded to.
Can this product be used as a code stock?	The system default is 'No'. Select "Yes" if this application can be used as a code stock.

This application is to: change a current listing/create a new listing:	This field is conditionally mandatory. Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. To create a new export-only product, select **Create a New listing:** If **Change a current listing:** is selected, the form will refresh to allow for the creation of a Grouping or Variation to a single current listing. See page 25 for further details.
AUST L:	This field is hidden until 'Change a current listing' is selected to the question above. Enter an AUST L number from which to create a new draft copy. Single click the "Search" button, the application form will populate with the details of the AUST L record entered.
Submission Cost:	This field will be automatically populated once an application is validated. It displays the submission cost

	of the application.
Application Status:	This field is populated by the system depending on the current status of the application.
Payment Exemption No:	This field is not mandatory. If permitted by the TGA, enter a payment exemption number, if an exemption is applicable to this application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.
Validation Report:	On Validating the application the system displays a validation report. Messages displayed will indicate any errors will the application. These errors must be fixed before the application can be submitted to the TGA.

Formulation Details:	Single click the 'Add' button to add a formulation to the application. Multiple formulations can be added. For details on the Formulation Details subform, refer to Page 49.
Manufacturer(s):	This field is mandatory. Single click the 'Add' button to add a manufacturer to the application. Multiple manufacturers can be added. Form details on the Manufacturers subform, refer to Page 477.

Product Details:	
Indications:	This is a mandatory field. Single click the 'Add' button to add an indication to the application. Multiple indications can be added. For details on the Indications subform, refer to Page 56.
Warnings:	This field is conditionally mandatory. Single click the 'Add' button to add a warning to the application. Multiple warnings can be added. For details on the Warnings subform, refer to Page 57.
Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
6. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

Creating a Change to Multiple Current Listings

A Change Multiple Listing application is used to make specific changes to multiple existing ARTG listings. The details that can be changed include the product name and any common manufacturing steps. Additionally new common manufacturers can be added to all selected ARTG listings.

How to create a Change to Multiple-Current Listings

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link under the Portal select the 'S.26a – Solely for Export' link .
2. The 'S.26a Solely for Export' application types will be displayed. Select the 'Change Multiple Solely for Export Listings Application' link.
3. The 'Change Multiple Solely for Export Listings Application' form will be displayed in edit mode, ready for information to be entered (see Figure 14 below).
4. Complete the Application by entering information into the following fields

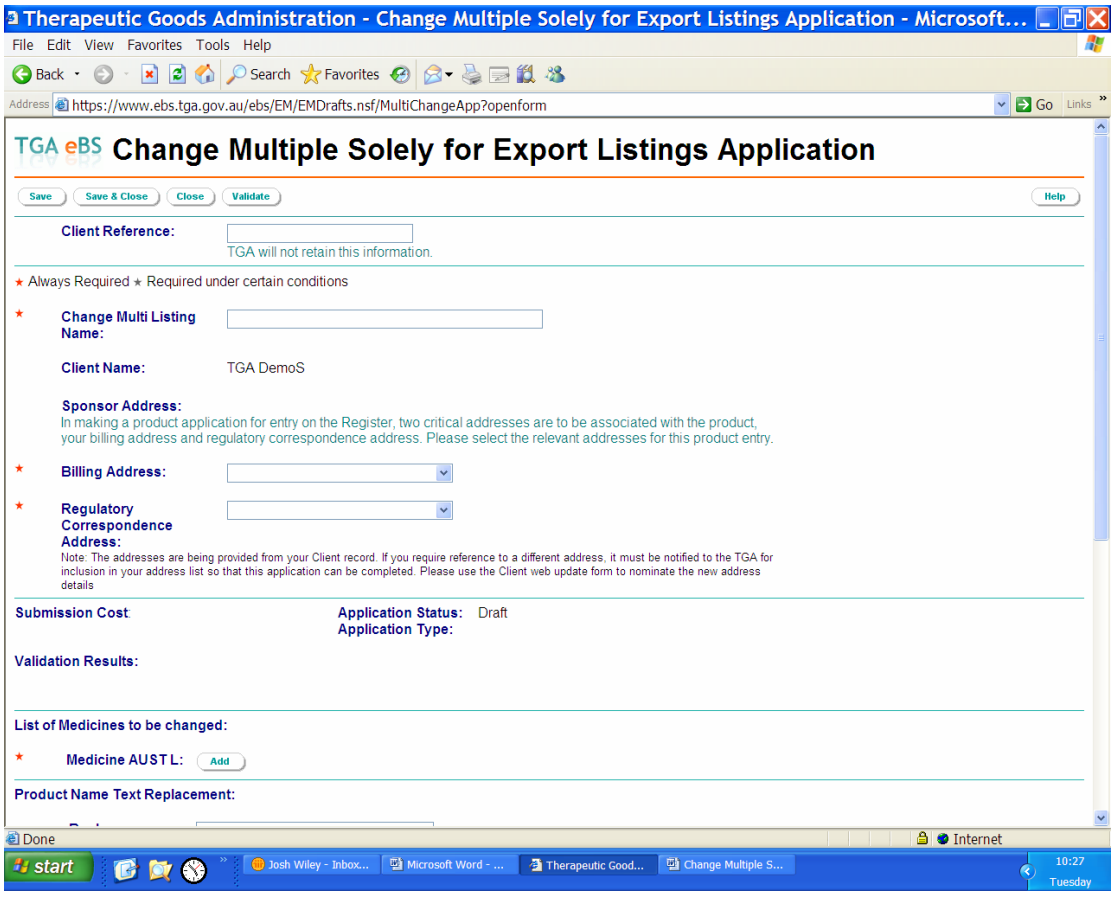

Therapeutic Goods Administration - Change Multiple Solely for Export Listings Application - Microsoft...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebs.tga.gov.au/ebs/EM/EMDrafts.nsf/MultiChangeApp?openform
Go Links
TGA eBS Change Multiple Solely for Export Listings Application
Save
Save & Close
Close
Validate
Help
Client Reference:
TGA will not retain this information.
★ Always Required ★ Required under certain conditions
Change Multi Listing Name:
Client Name:
TGA DemoS
Sponsor Address:
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant addresses for this product entry.
Billing Address:
Regulatory Correspondence Address:
Note: The addresses are being provided from your Client record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details
Submission Cost
Application Status: Draft
Application Type:
Validation Results:
List of Medicines to be changed:
Medicine AUST L:
Add
Product Name Text Replacement:
Done
Internet
start
Josh Wiley - Inbox...
Microsoft Word - ...
Therapeutic Good...
Change Multiple S...
10:27
Tuesday

Figure 14. Change Multiple Solely for Export Listings Application

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Change Multi Listing Name:	This field is mandatory. Enter the name of the Change Multiple Listing draft. This name will be used to identify the set of current listings that will have the changes made to them. However, it will not be written to the ARTG.
Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export-Only Medicines system.
Billing Address:	This field is Mandatory. Select the appropriate address from the drop down list.
Regulatory Contact Address:	This field is Mandatory. Select the appropriate address from the drop down list.

Submission cost:	This field will be automatically populated once an application is validated. It displays the submission cost of the application.
Application Status:	This field is populated by the system depending on the current status of the application.
Application type:	Displays the final type of application when the draft application has been entered and validated (e.g. New, Grouping, Variation). Note: this field only appears when the Application status is valid.
Validation Results:	On Validating the application the system displays a validation report. Messages displayed will indicate any errors will the application. These errors must be fixed before the application can be submitted to the TGA.

List of Medicines to be Changed:	
Medicine AUST L:	Single click the ‘Add’ button to add an existing medicine AUST L to the application. Multiple medicines can be added. Medicines selected will be displayed in a table.

Product Name Text Replacement:	
Replace:	Enter the part of the product name text to be replaced. This text must be common to the names of all the products selected.
With:	Enter the new text to use in the product name.

Common Manufacturing Steps:	
Remove Steps:	Only manufacturing steps that are common to all the selected medicines will be displayed in the table. Delete any common manufacturing steps listed in the table as required. Single click the 'Add' button to add common manufacturing steps to all of the selected medicines.

New Manufacturers:	
Manufacturers:	Single click the 'Add' button to add common manufacturers to all of the selected medicines. For details on the Manufacturers subform, refer to Page 47.

Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

5. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
6. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
7. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

Application Subforms

The Ingredient Subform

From the Application form, clicking the 'Add' button beside the Ingredient field will provide the user with the Ingredient Subform as shown in the Figure below:

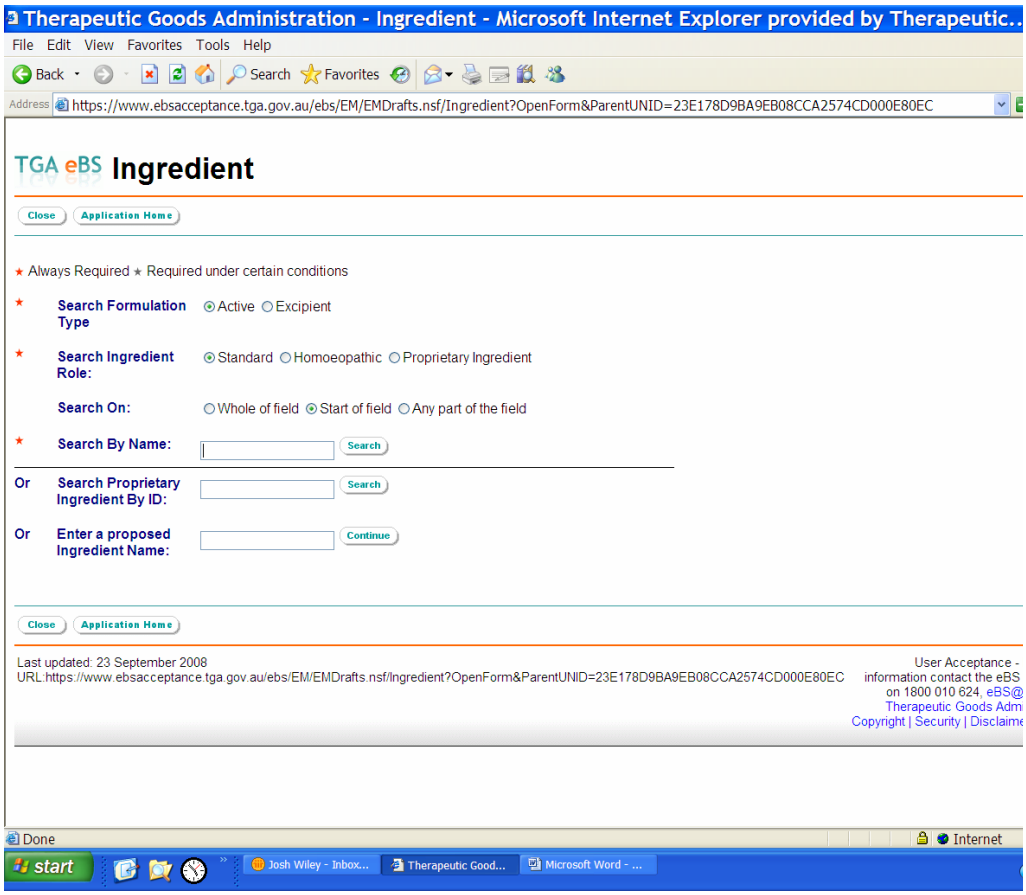

Therapeutic Goods Administration - Ingredient - Microsoft Internet Explorer provided by Therapeutic..
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/Ingredient?OpenForm&ParentUNID=23E178D9BA9EB08CCA2574CD000E80EC
TGA eBS Ingredient
Close Application Home
* Always Required * Required under certain conditions
* Search Formulation Type Active Excipient
* Search Ingredient Role: Standard Homoeopathic Proprietary Ingredient
Search On: Whole of field Start of field Any part of the field
* Search By Name: Search
Or Search Proprietary Ingredient By ID: Search
Or Enter a proposed Ingredient Name: Continue
Close Application Home
Last updated: 23 September 2008
URL:https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/Ingredient?OpenForm&ParentUNID=23E178D9BA9EB08CCA2574CD000E80EC
User Acceptance - information contact the eBS on 1800 010 624, eBS@
Therapeutic Goods Adm
Copyright | Security | Disclaime
Done
Internet
start
Josh Wiley - Inbox...
Therapeutic Good...
Microsoft Word - ...

Figure 15. Ingredient Subform

To enter an Ingredient onto the application form:

1. Select the type of ingredient (i.e. Active or Excipient) from the 'Search Formulation Type' radio buttons.
2. Select the ingredient role from the 'Search Ingredient Role' radio buttons

Searching for an ingredient can be made in the following ways:

- Search by Name – This text field allows the user to enter either the whole name of the Ingredient, the start of the name or any part of the name (depending on the choice made on the 'Search On' field). Once populated click the 'Search' button to the right of the field.
- Search Proprietary Ingredient (PI) by ID – enter the PI TGA's assigned ID and click the 'Search' button to the right of the field.
- Enter a proposed Ingredient Name – if it is not currently an approved ingredient with the TGA, enter the proposed name of the ingredient and click the 'Continue' button to the right of the field.

Once the search is completed the following form will be provided:

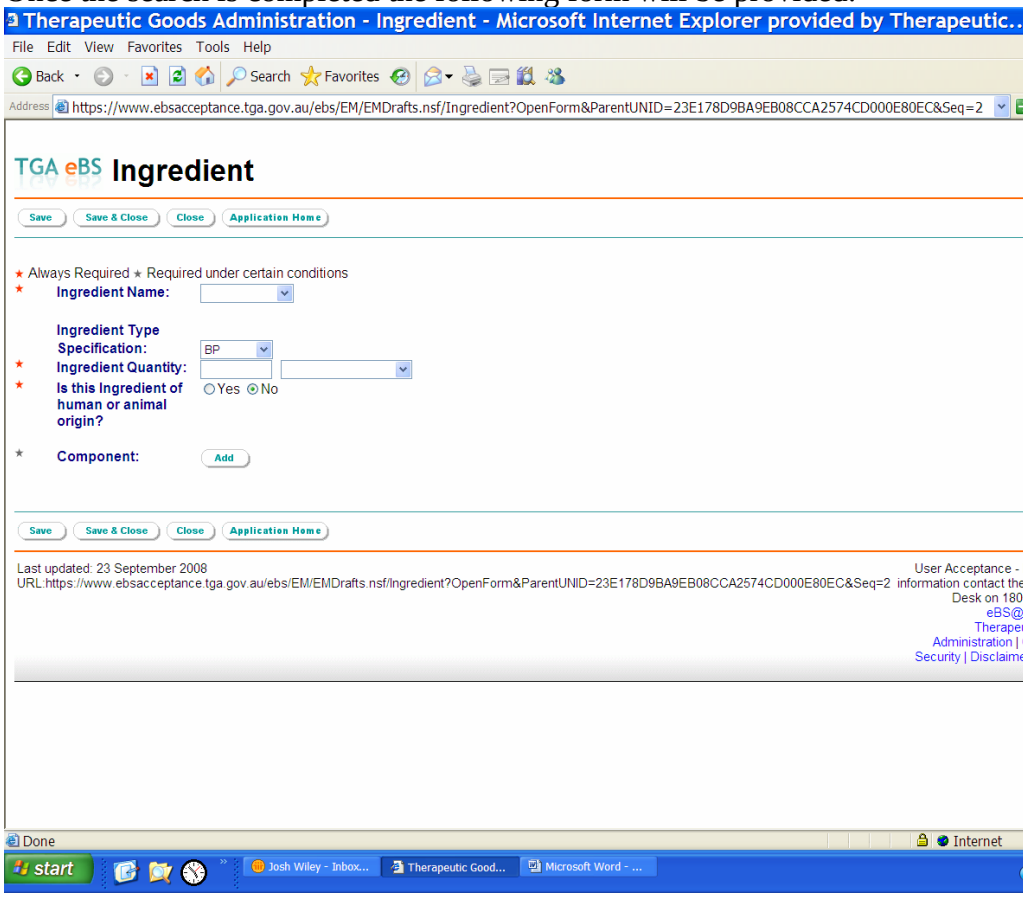


Figure 16. Ingredient subform after a successful search

To complete the form use the following table for information:

Field	Description
Ingredient Name	Use the drop-down box to select the Ingredient name from the search results. If only one ingredient was found this will appear in the field.
Proprietary Ingredient ID	*This field will only appear if the ingredient role selected during the search is 'Proprietary Ingredient'.* This field will be automatically populated once the Ingredient Name is selected.
Supplier ID	*This field will only appear if the ingredient role selected during the search is 'Proprietary Ingredient'.* This field will automatically populate once the Ingredient Name is selected.
Ingredient Role	*This field will only appear if the ingredient is a proposed ingredient.* Select between 'Active', 'Excipient' and 'Active Homeopathic'.

Ingredient Type:	This field will be automatically populated once the Ingredient Name is selected.
Ingredient Type Specification:	Select the specifications from the drop-down list provided.
Ingredient Quantity	Enter the quantity in the first field and use the drop-down list to select the quantity measure in the second field.
Plant Part	*This field will only appear if the ingredient type is of a herbal origin.* Select the appropriate plant part that the ingredient is derived from.
Plant Preparation	*This field will only appear if the ingredient type is of a herbal origin.* Select the appropriate preparation used to extract the ingredient.
Equivalent Preparation	*This field will only appear if the ingredient type is of herbal origin.* Select the appropriate equivalent preparation type. Some ingredients will require the declaration of an equivalent for validation, and others will allow only specific equivalent types to be declared. 'Not declared' is the default selection. 'Fresh', 'Dry', 'Juice fresh' and 'Juice dry' may be selected.
Equivalent Quantity	Enter the quantity in the first field and use the drop-down list to select the quantity measure in the second field.
Final Preparation Ratio	*This field will only appear if the ingredient type is of herbal origin.* Enter a number in the text field to complete the ratio. This ratio must be the same as the ratio of the ingredient quantity to equivalent quantity.
Is this ingredient of human or animal origin?	The system default is 'No'. Use the radio buttons select if this ingredient contains human or animal origins.

Preparation Steps	*This field will only appear if the declaration of preparation steps for the selected plant preparation is appropriate.* Single click the 'Add' button to add a preparation step. For further details on the preparation step subform, refer to page 51 Once preparation steps are added to the table, the name of the preparation step will be a linked to the step details. To edit the preparation step, select the link. To remove the Preparation Step, click on 'Delete' in the table.
Carrier	*This field will only appear if the declaration of carriers for the selected plant preparation is appropriate.* Single click the 'Add' button to add a carrier. For further details on the carrier subform, refer to page 53 Once carriers are declared, the name of each carrier will be a link to edit the carrier details. There will also be a 'Delete' link available to remove the carrier.
Component:	Select the 'Add' button to add a component. This will provide a Component subform; refer to Page 54 for details on this form. Once a component is declared, its name will act as a link to the component subform for editing purposes. There will also be a 'Delete' link available to remove the component.
Remaining Restricted Solvent *(only required if your product is to be listed under Section 26a)*	*This field will only appear if the declaration of remaining restricted solvents is appropriate for the selected plant preparation.* Single click the 'Add' button to add a restricted solvent. For further details on the remaining restricted solvent subform, refer to page 55 Once restricted solvents are declared, the name of each solvent will be a link to edit the solvent details. There will also be a 'Delete' link available to remove the solvent.

The Manufacturers Subform

From the Application form, clicking the 'Add' button beside the Manufacturers field will provide the user with the Manufacturer Subform.

1. Use the radio buttons to identify if the Manufacturer is Australian or Overseas.
   Depending on the selection, one of the following two forms will be provided:

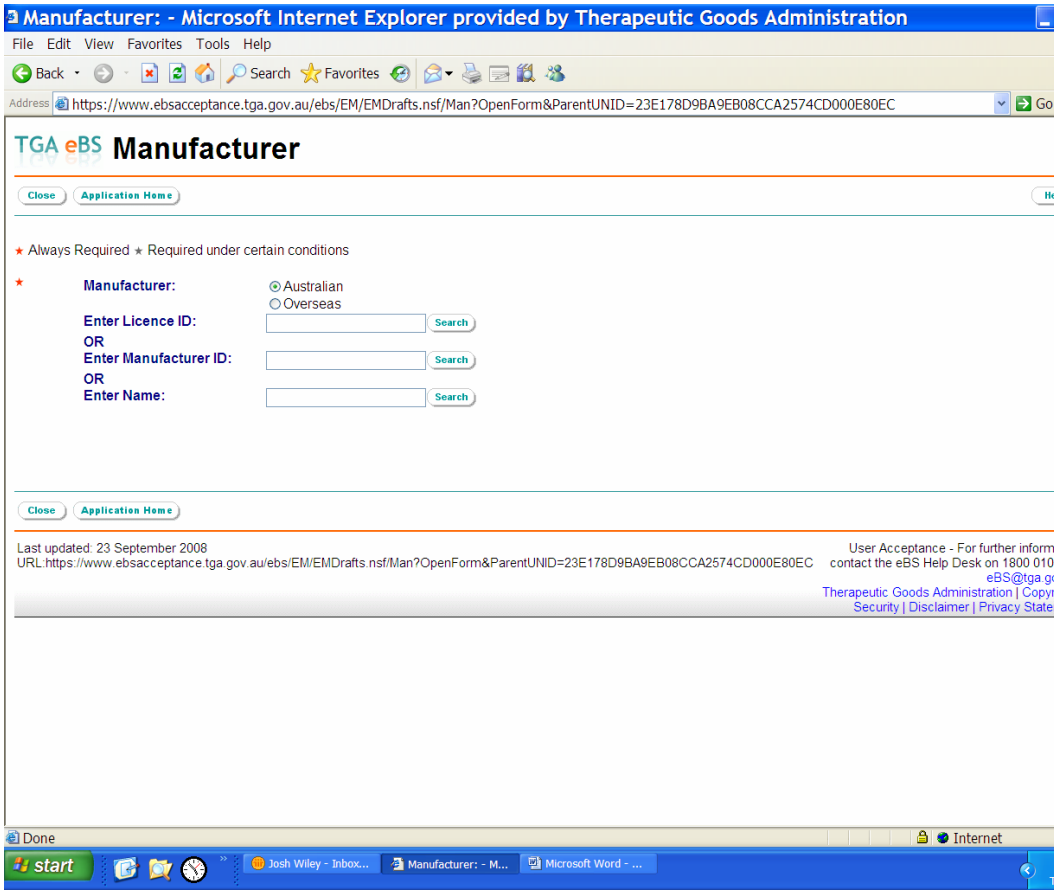
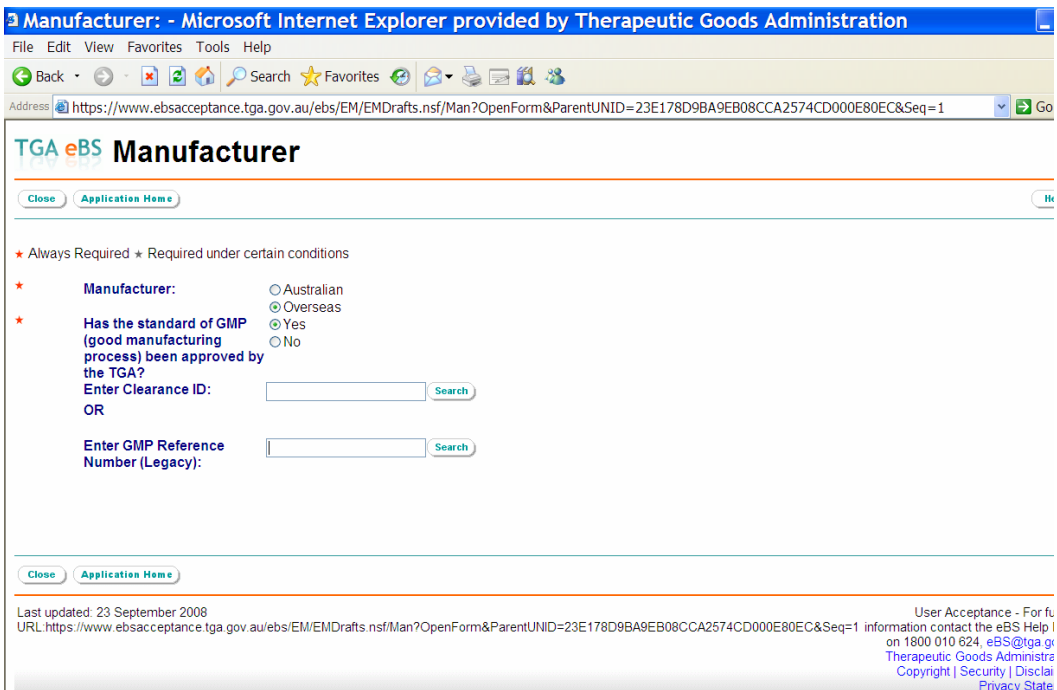


Figure 17. Australian Manufacturer Subform

2. For the Australian Manufacturing form, enter either the Manufacturer ID or the Manufacturers Name and press the 'Search button beside the form.



Note: The GMP Approval field, if ‘No’ is selected another subform appears requiring details about the overseas manufacturer.
If ‘Yes’ is selected, Enter either the Clearance ID number prefaced with MI-…. Or the GMP Reference Number in the field provided and press the ‘Search’ button.

Complete the details of the forms and ‘Save & Close’ the form. The application will be updated with the information.

The Formulation Subform

From a composite pack application form, clicking the 'Add' button beside the Formulation field will provide the user with the Formulation subform as shown in the figure below.

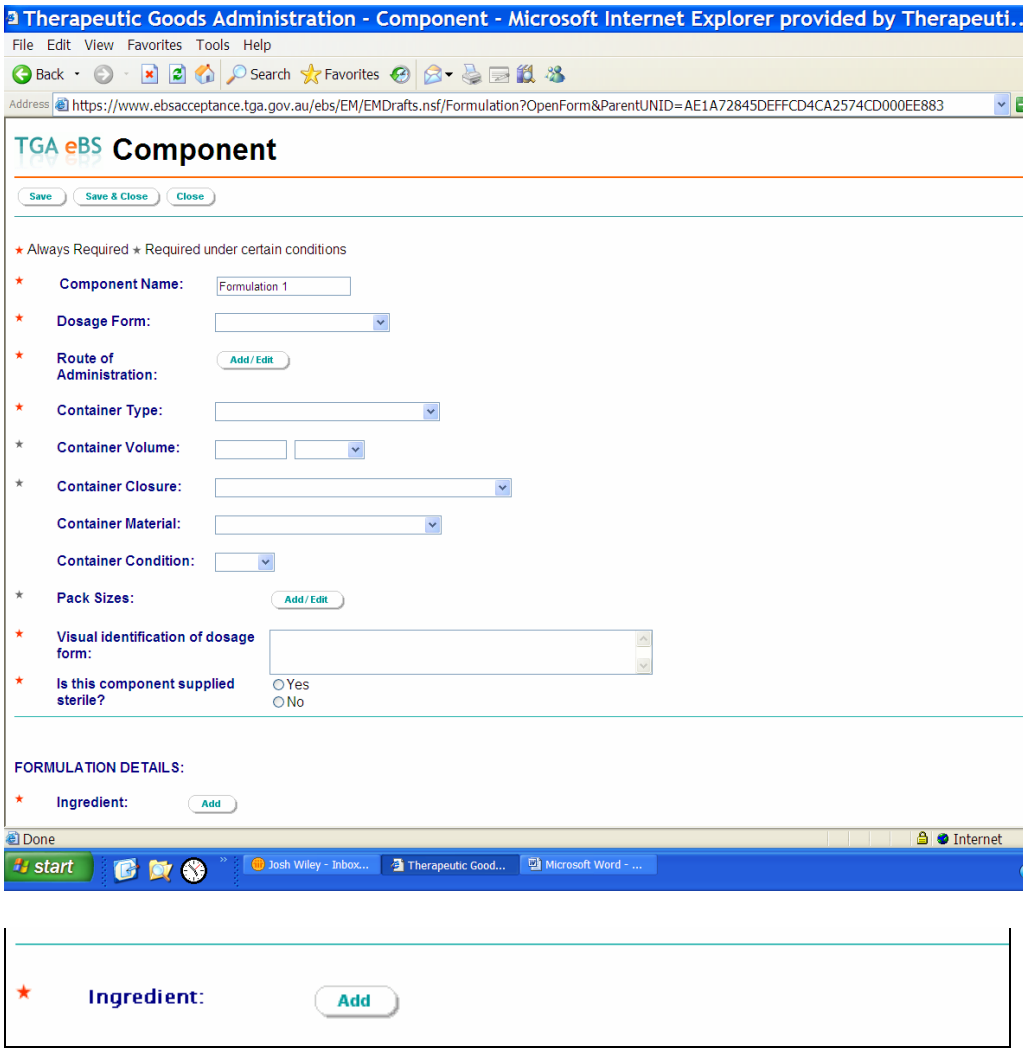


Figure 19. Formulation Subform

To enter a formulation onto the application form complete the following fields.

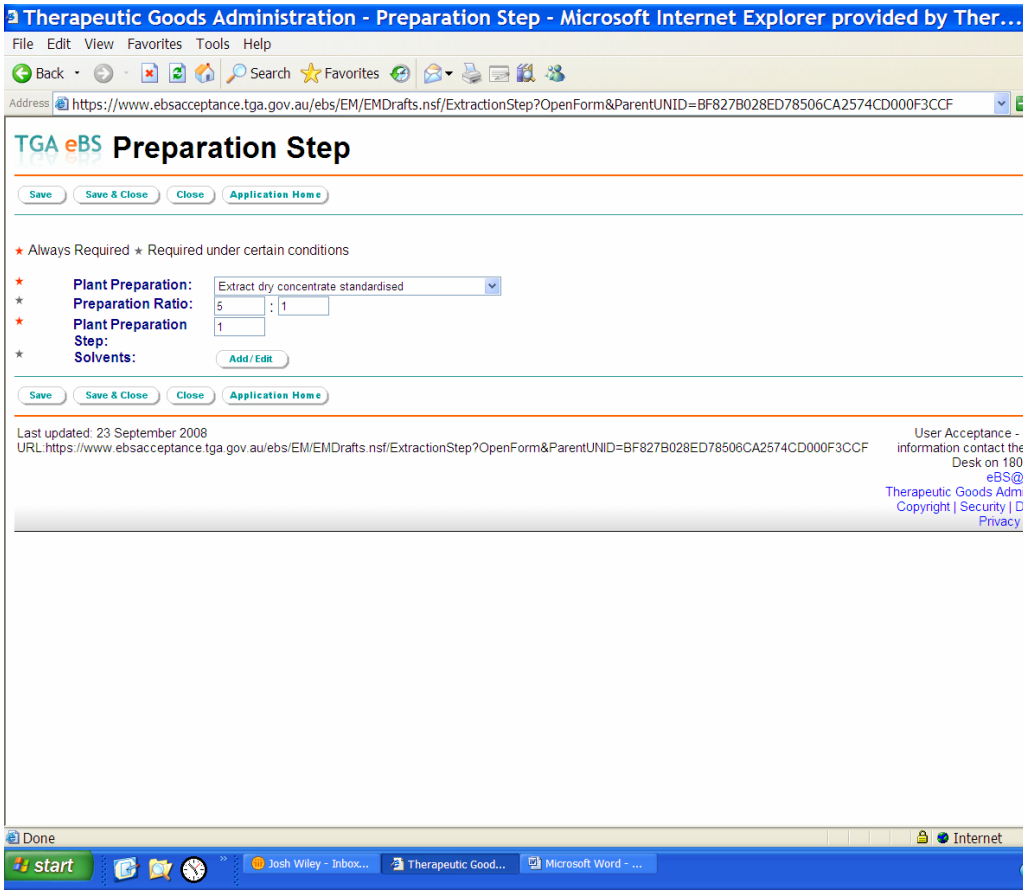
Field	Description
Formulation Name	This field is mandatory. Enter the name for the formulation. This name will assist to differentiate between multiple formulations in a composite pack at a quick glance.
Formulation Details:	
Dosage Form	This field is mandatory. Use the drop down arrow to select the appropriate dosage form for the formulation.

Route of Administration	This field is mandatory. Single click the 'Add' button and the route of administration table will be provided. Multiple routes of administration can be added. Select the 'Save & Close' button to return to the application form.
Container Type	This field is mandatory. Use the drop down arrow to select the appropriate container type for the formulation.
Container Volume	This field is conditionally mandatory. Its status is determined by the rules applied to the ingredients included in the formulation. Enter the numeric quantity for the container volume, then use the drop down arrow to select the appropriate volume measure.
Container Closure/ Container Material/ Container Condition	These fields are conditionally mandatory. If desired, select the appropriate description from each corresponding drop-down list.
Visual identification of dosage form:	This field is mandatory. Enter a text description of the visual identification of dosage form
Is this component supplied sterile?	This field is mandatory. Select 'Yes' or 'No'. If 'Yes' is selected then Sterility Description field that appear, must be completed.
Sterility Description:	This field is conditionally mandatory. If selecting 'Yes' to the question above, this field will become available. Select a description from the drop-down list.
Ingredient:	This field is mandatory. Single click the 'Add' button to add an ingredient to the application. Multiple ingredients can be added. For details on the Ingredient Subform refer to Page 43

The Preparation Step Subform

(used for herbal and homeopathic herbal ingredients)

From an ingredient subform, clicking the 'Add' button beside the Preparation Step field will provide the user with the Preparation Step subform as shown in the figure below.


Therapeutic Goods Administration - Preparation Step - Microsoft Internet Explorer provided by Ther...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/ExtractionStep?OpenForm&ParentUNID=BF827B028ED78506CA2574CD000F3CCF
TGA eBS Preparation Step
Save Save & Close Close Application Home
★ Always Required ★ Required under certain conditions
Plant Preparation: Extract dry concentrate standardised
Preparation Ratio: 5 : 1
Plant Preparation Step: 1
Solvents: Add / Edit
Save Save & Close Close Application Home
Last updated: 23 September 2008
URL:https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/ExtractionStep?OpenForm&ParentUNID=BF827B028ED78506CA2574CD000F3CCF
User Acceptance - information contact the Desk on 180
eBS@
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Josh Wiley - Inbox...
Therapeutic Good...
Microsoft Word - ...

Figure 20. Preparation Step Subform

To enter the details for a preparation step, complete the following fields:

Field	Description
Plant Preparation	This field is mandatory. If the preparation selected for the ingredient allows only for a single preparation step, this field will be locked from editing, and will be automatically populated with the value selected for the ingredient.
	Otherwise, if the preparation selected for the ingredient allows for multiple preparation steps, this field will display as a drop-down list which has a default value equivalent to the preparation selected for the ingredient.
Preparation Ratio	These fields are conditionally mandatory. The values in each field are by default the same as the ratio for the final preparation ratio.
Plant Preparation Step	This field is mandatory. The number entered here determines the sequence of the preparation steps when multiple preparation steps appear in an ingredient.

Solvents	This field is conditionally mandatory. Single click the "Add/Edit" button and the solvent subform will be provided. For details on the solvent Subform refer below.

The Solvent Subform

From a preparation step subform, clicking the 'Add/Edit' button beside the Solvent field will provide the user with the Solvent subform as shown in the figure below.

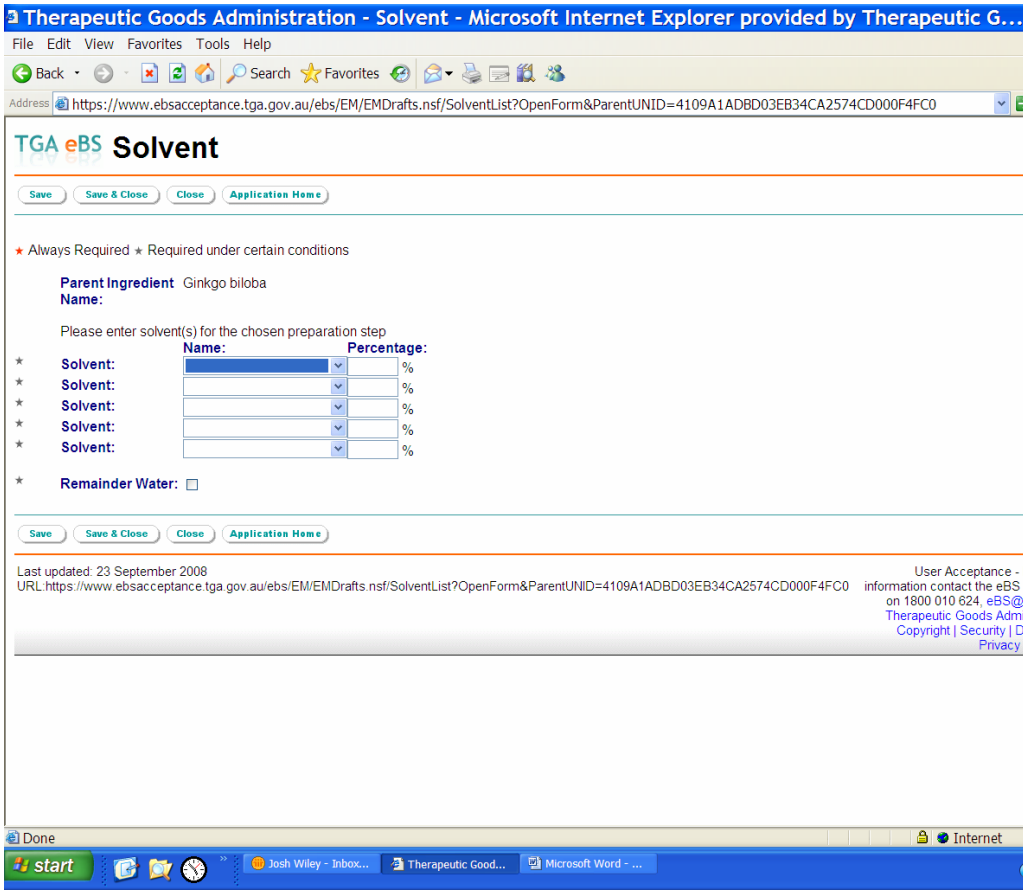
Therapeutic Goods Administration - Solvent - Microsoft Internet Explorer provided by Therapeutic G...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/SolventList?OpenForm&ParentUNID=4109A1ADBD03EB34CA2574CD000F4FC0
TGA eBS Solvent
Save Save & Close Close Application Home
* Always Required * Required under certain conditions
Parent Ingredient Name: Ginkgo biloba
Please enter solvent(s) for the chosen preparation step
Name: Percentage:
* Solvent: %
* Solvent: %
* Solvent: %
* Solvent: %
* Solvent: %
* Remainder Water:
Save Save & Close Close Application Home
Last updated: 23 September 2008
URL:https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/SolventList?OpenForm&ParentUNID=4109A1ADBD03EB34CA2574CD000F4FC0
User Acceptance - information contact the eBS on 1800 010 624, eBS@
Therapeutic Goods Adm
Copyright | Security | D
Privacy
Done
Internet
start
Josh Wiley - Inbox...
Therapeutic Good...
Microsoft Word - ...

Figure 21. Solvent Subform

To enter the solvent details for a preparation step, complete the fields as detailed below.

Field	Description
Solvent	Each of these fields is conditionally mandatory. At least one solvent needs to be selected, and its corresponding percentage entered. Percentages must add up to exactly 100.
Remainder Water	This field is conditionally mandatory. Checking this field will create Water – purified as a solvent, with a percentage value to ensure that the 100 percent total is reached. If no other solvents are entered, this will set the percentage of Water-purified to 100.

The Carrier Subform

From an ingredient subform, clicking the 'Add' button beside the Carrier field will provide the user with the Carrier subform as shown in the figure below.

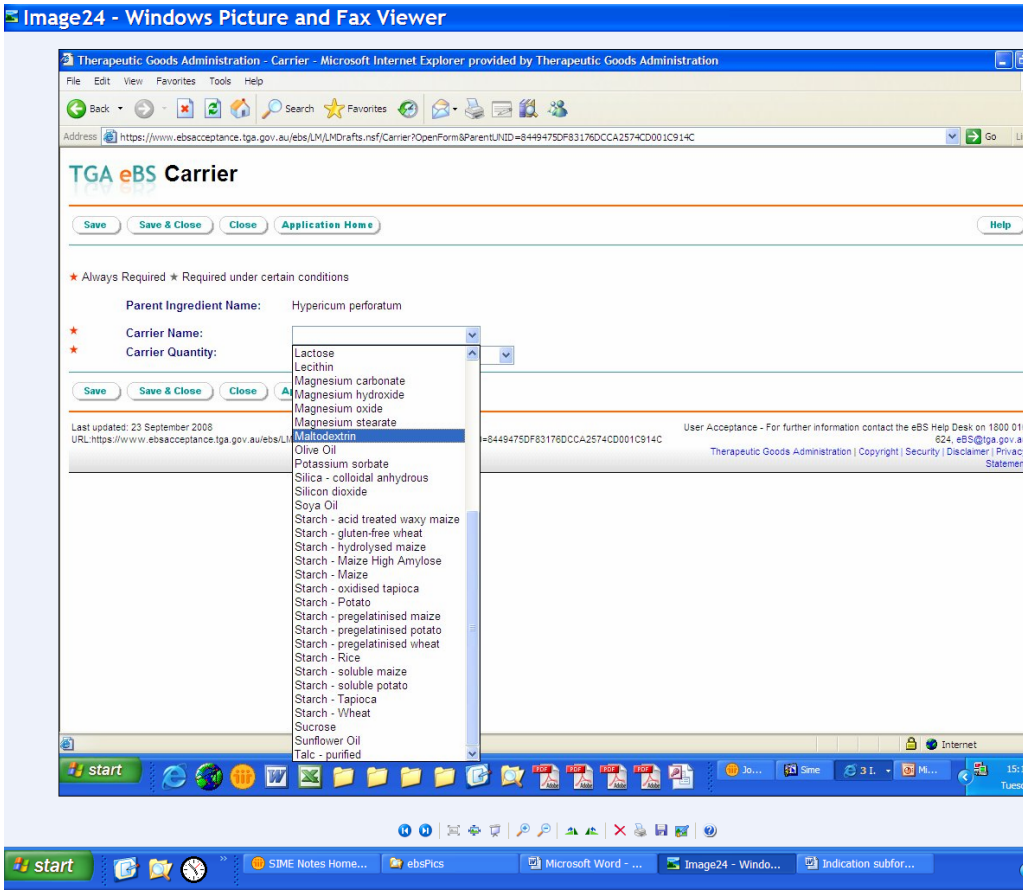

Figure 22. Carrier Subform

To enter the carrier details for an ingredient, complete the fields as detailed below.

Field	Description
Parent Ingredient Name	This field is automatically populated with the parent ingredient name.
Carrier Name	This field is mandatory. Click on the drop-down arrow to select the carrier.
Carrier Quantity	This field is mandatory. Enter the numeric quantity value and click on the drop-down arrow to select the unit of measurement.

The Component Subform

From an ingredient subform, clicking the 'Add' button beside the Component field will provide the user with the Component subform as shown in the figure below.

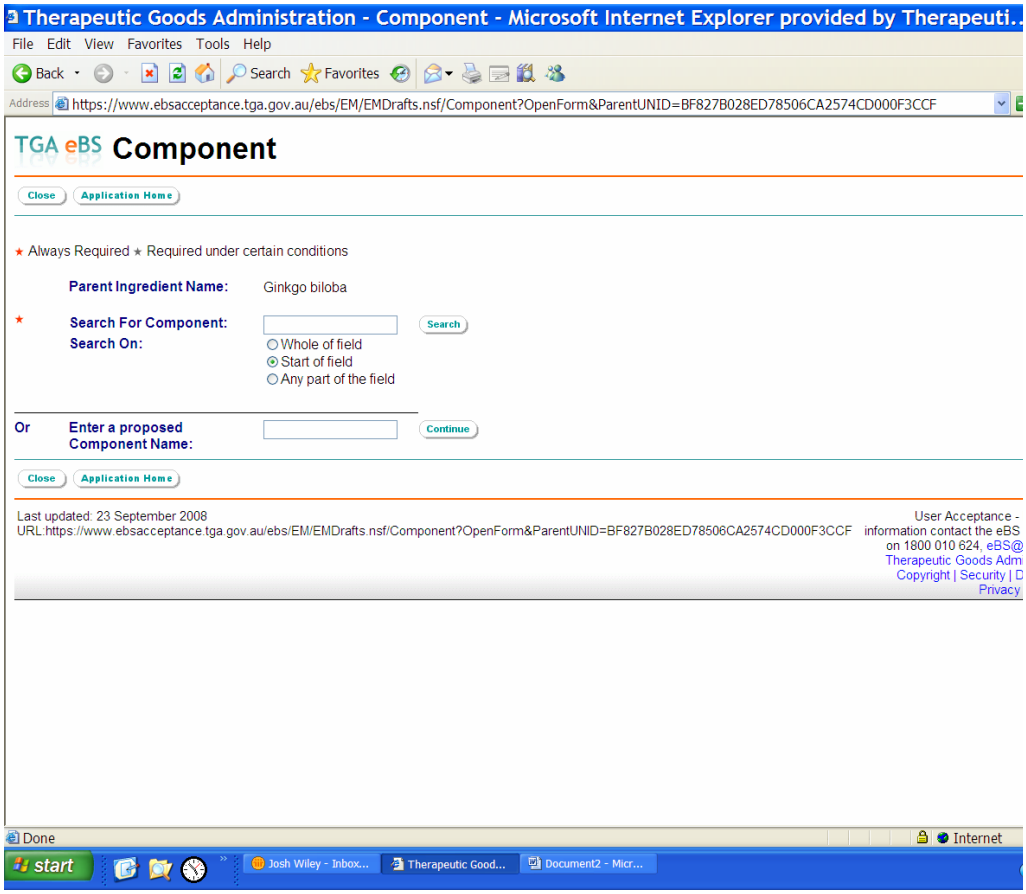

Figure 23. Component Subform

To enter an Ingredient onto the application form:

1. Enter the start of, a part of or all of the component name in the 'Search for Component' text field.
2. Single click the 'Search' button.

If the search is successful the Component subform will refresh to provide the following fields.

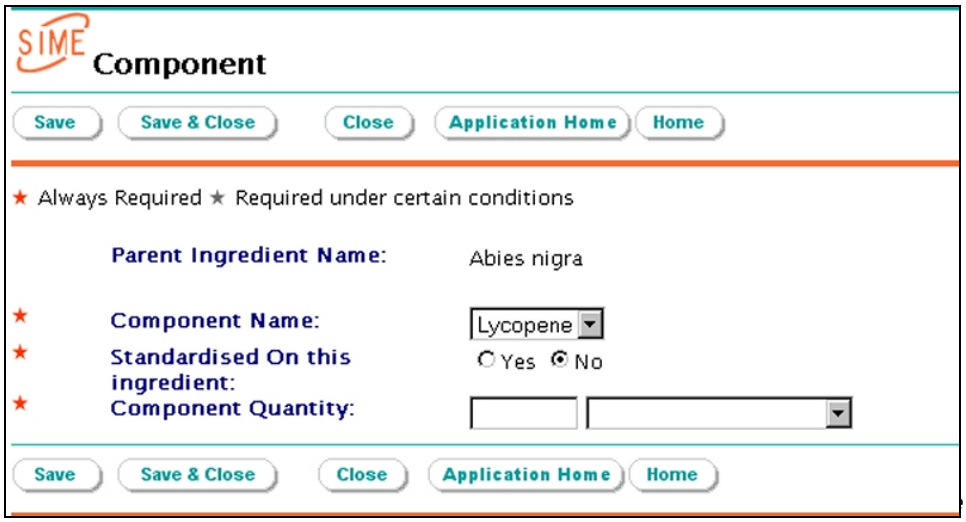
SIME Component
Save Save & Close Close Application Home Home
★ Always Required ★ Required under certain conditions
Parent Ingredient Name: Abies nigra
Component Name: Lycopene
Standardised On this ingredient: Yes No
Component Quantity:
Save Save & Close Close Application Home Home

Figure 3. Component Subform after successful component search

To enter the carrier details for a component, complete the fields as detailed

Field	Description
Parent Ingredient Name	This field is automatically populated with the parent ingredient name.
Component Name	This field is mandatory. Select from the list of components returned by the search.
Standardised on this Ingredient	This field is mandatory. This field defaults to 'No'. Select 'Yes' to standardise the parent ingredient with this component.
Component Quantity	This field is mandatory. Enter the numeric quantity value and click on the drop-down arrow to select the unit of measurement.

The Remaining Restricted Solvent Subform

From an ingredient subform, clicking the 'Add' button beside the Remaining Restricted Solvent field will provide the user with the Remaining Restricted Solvent subform as shown in the figure below.

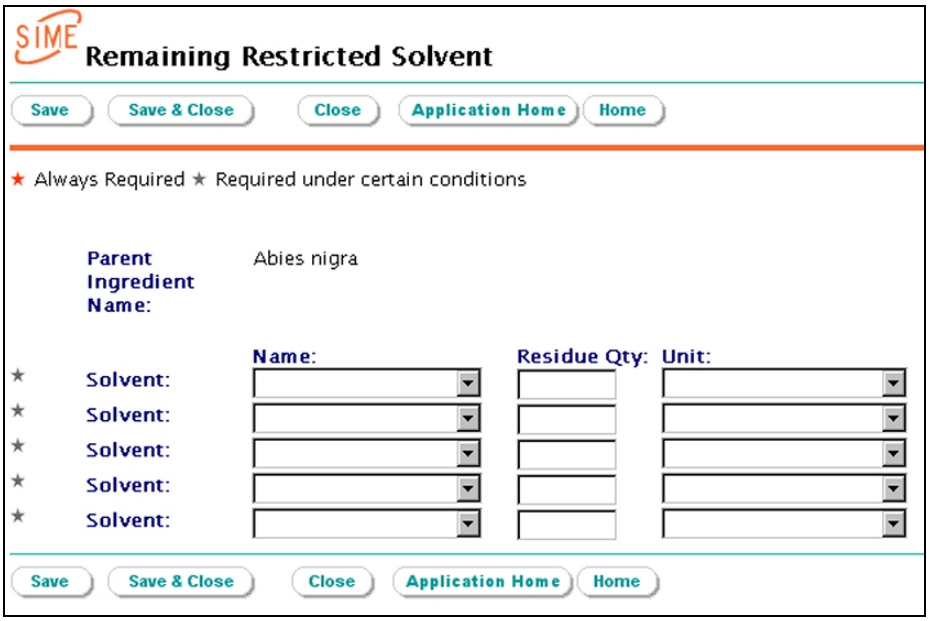

Figure 25. Remaining Restricted Solvent Subform

To enter the restricted solvent details for an ingredient, complete the fields as detailed below.

Field	Description
Parent Ingredient Name	This field is automatically populated with the parent ingredient name.
Solvent (Name, Residue Qty and Unit)	These fields are conditionally mandatory. Click on the drop-down arrow of the name field to select the solvent. Enter the numeric value of the residual quantity, and click on the drop-down arrow of the unit field to select the unit of measurement.

The Indications Subform

From an application subform, clicking the ‘Add’ button beside the Indications field will provide the user with the Indication subform as shown in the figure below.

(This subform is available for S26a application.)

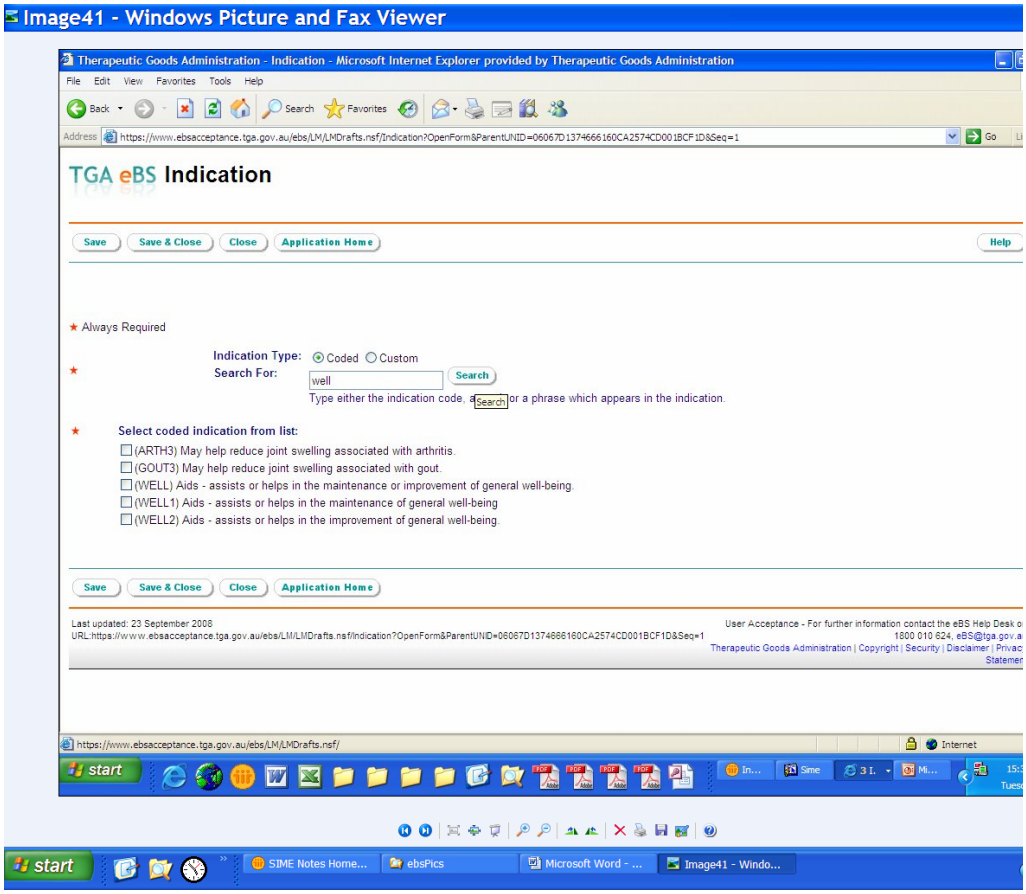
Image41 - Windows Picture and Fax Viewer
Therapeutic Goods Administration - Indication - Microsoft Internet Explorer provided by Therapeutic Goods Administration
TGA eBS Indication
Save
Save & Close
Close
Application Home
Help
Always Required
Indication Type:
Coded
Custom
Search For:
well
Search
Type either the indication code, a Search or a phrase which appears in the indication.
Select coded indication from list:
(ARTH3) May help reduce joint swelling associated with arthritis.
(GOUT3) May help reduce joint swelling associated with gout.
(WELL) Aids - assists or helps in the maintenance or improvement of general well-being.
(WELL1) Aids - assists or helps in the maintenance of general well-being
(WELL2) Aids - assists or helps in the improvement of general well-being.
Last updated: 23 September 2008
User Acceptance - For further information contact the eBS Help Desk
Therapeutic Goods Administration | Copyright | Security | Disclaimer | Privac
Statemer
start
SIME Notes Home...
ebsPics
Microsoft Word - ...
Image41 - Windo...

Figure 26. Indication Subform with coded indication selection made and indication options provided as a result of the text entered “well”

To enter the indication details for an application, complete the fields as detailed below.

Field	Description
Indication Type	Select either coded or custom. If ‘Coded’ is selected, enter a code or term in the ‘Search For’ field to search for a coded indication. If ‘Custom’ is selected, the ‘Enter custom indication text’ field will be displayed.
Enter custom indication text	*This field will only be displayed if ‘Custom’ is selected in the ‘Indication Type’ field.* This field is mandatory. Enter the custom indication text here.

Search For	*This field will only be displayed if 'Coded' is selected in the 'Indication Type' field.* This field is mandatory. Enter the code or term to search upon and single-click 'Search'. If the search is successful a list of coded indications will appear.
Select coded indication from list	*This field will only be displayed after a successful search.* This field is mandatory. Select at least one coded indication by placing a check against it. If none of the indications in the list are appropriate, enter a new code/term in the 'Search For' field and single-click 'Search' again.

The Warnings Subform

(This subform is available for S26a applications)

From an application subform, clicking the 'Add' button beside the Warnings field will provide the user with the Warning subform as shown in the figure below.

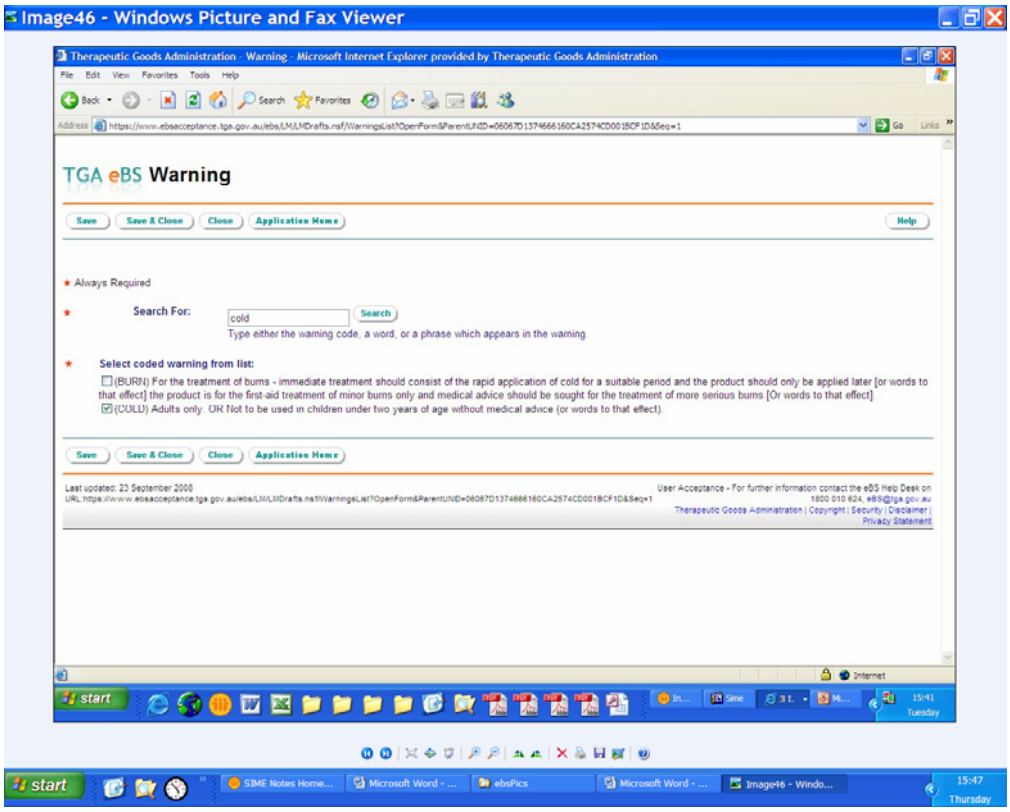
Image46 - Windows Picture and Fax Viewer
Therapeutic Goods Administration - Warning - Microsoft Internet Explorer provided by Therapeutic Goods Administration
TGA eBS Warning
Save
Save & Close
Close
Application Home
Help
Always Required
Search For:
cold
Search
Type either the warning code, a word, or a phrase which appears in the warning.
Select coded warning from list:
(BURN) For the treatment of burns - immediate treatment should consist of the rapid application of cold for a suitable period and the product should only be applied later [or words to that effect] the product is for the first-aid treatment of minor burns only and medical advice should be sought for the treatment of more serious burns [Or words to that effect]
(COLD) Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
start

Figure 27. Warning Subform displaying warning options when "cold" has been selected as search word.

To enter the warning details for an application, complete the fields as detailed below.

Field	Description
Search For	This field is mandatory. Enter the code or term to search upon and single-click ‘Search’. If the search is successful a list of coded warnings will appear.
Select coded warning from list	*This field will only be displayed after a successful search.* This field is mandatory. Select at least one coded warning by placing a check against it. If none of the warnings in the list are appropriate, enter a new code/term in the ‘Search For’ field and single-click ‘Search’ again.

Export Certificates

New Application

The Certificate of Pharmaceutical Product (CPP) Application Form

From this form, sponsors or agents can draft and validate an application for a Certificate of Pharmaceutical Product (CPP).

Creating a CPP Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link, under the Portal select the 'Export Certificates' link
2. The 'Export Certificate' application types will be displayed.
3. Click on the 'Application for Certificate of Pharmaceutical Product' link
4. The 'Certificate of Pharmaceutical Product' application form will be displayed in edit mode, ready for information to be entered (see figure 28 below).

Complete the application using the information in the following table

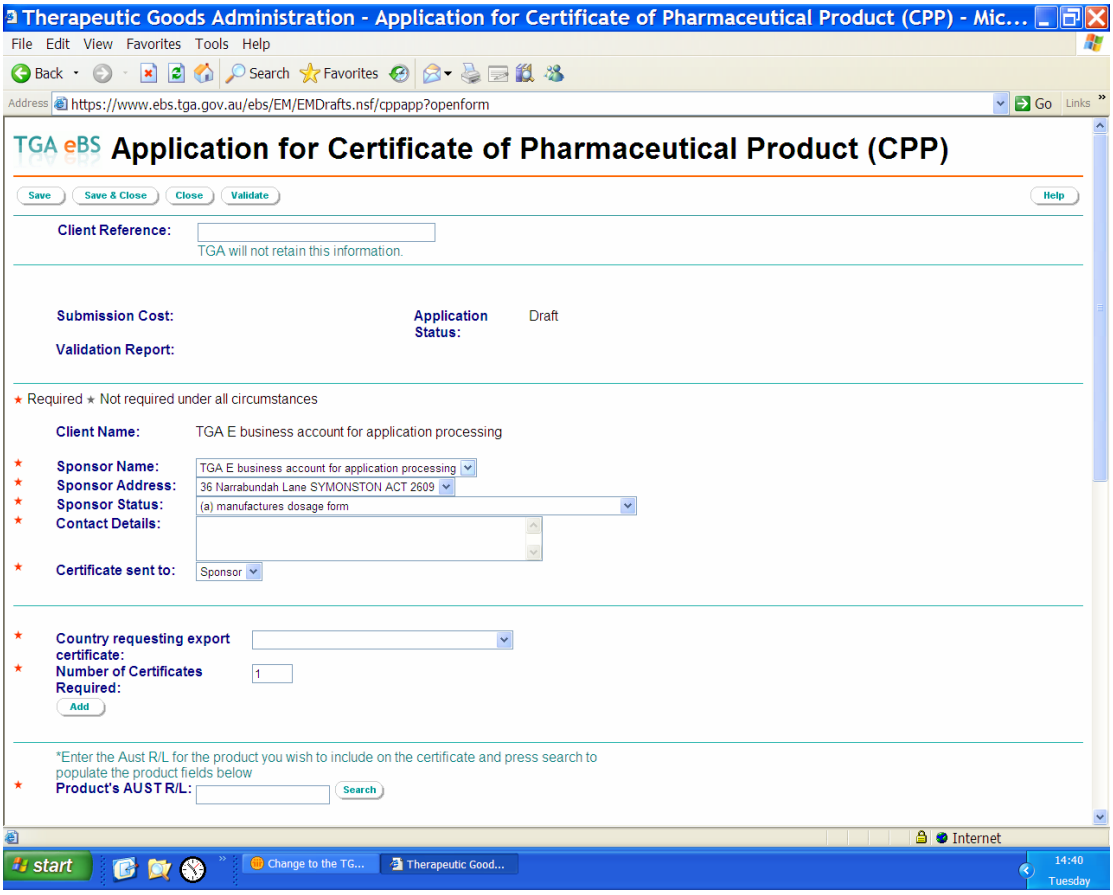

Figure 28. Application for Certificate of Pharmaceutical Product form

Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Submission cost:	Once the application has been validated, this field displays the submission cost of the application.

Application Status:	This field is populated by the system following validation, depending on the current status of the application.
Validation Report:	On validating the application the system displays a validation report. Messages displayed will indicate any errors with the application. These errors must be fixed before the application can be submitted to the TGA.

Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export Electronic Lodgement system.
Sponsor Name:	This field is mandatory if the application is being completed by an Agent. Select the appropriate sponsor name from the drop down list.
Sponsor Address:	This field allows for the selection of a street address registered to the sponsor. The selected address is the address that will appear on the certificate.
Sponsor Status:	This field indicates the role of the sponsor in the production of the product. Options are: (a) Manufactures dosage form. (b) Packages, labels and/or releases for supply dosage form manufactured by independent manufacturer. (c) Is involved in none of the above. *If (a) is selected please ensure that the sponsor address selected belongs to a location that is registered and is appropriately licenced for the manufacturing of the chosen product's dosage form/s.*

Display Dosage Form Manufacturer Details?:	*This field will only appear if option (b) or (c) is selected for the sponsor status.* This field offers three choices for the inclusion of the dosage form manufacturer's details: 'Suppress details from certificate': Select this option if you wish to keep the dosage form manufacturer details confidential. 'See Schedule 2 for manufacturing details': Select this option for the words "See Schedule 2" to appear on the certificate. Ensure that you elect to show some or all of the manufacturers listed in the ARTG record for this product on this Schedule. 'One of the manufacturers recorded against the AUSTL/R selected': Select this option to enable one of the manufacturers listed in the ARTG record to be selected in the 'Select manufacturer to appear on certificate' field further down the form.
Contact details:	This field is Mandatory. The name and telephone number of the person who is to be contact for any queries relating to this application are preferred here.
Certificate sent to:	This selects whether the certificate is delivered to the sponsor or a third party. If the Other option is selected the form will refresh with an extra field for the name and address of the recipient.
Country requesting export certificate**:**	Select the name of the country requesting an export certificate from the drop-down list, then complete the following field.
Number of Certificates Required:	Please supply the correct number of certificates required by each importing country. Click the 'Add' button to add this request to the form. **Repeat** to add more than one Country to the request. ***Note***: If the 'Add' button is not used, the certificate request for the country will not be added to the CPP.

Product's AUST R/L:	Enter the AUST R or L of the product the certificate will be created for then click 'Search' to populate other fields. If the AUST R/L is not valid an error message will appear.
Product name:	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.
Dosage form:	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.
Container:	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.
Date commenced in the ARTG:	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.
Marked for Export Only?	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.

Is this product on the market in Australia?	If 'Yes' is selected for this question, there is no requirement to supply a reason (as listed below), however if the product is not on the market in Australia, 'No' must be selected and then one or more reasons why must also be selected.
Reasons the product is not on the market in Australia:	Select one or more reasons why the product is not on the market in Australia. Most reasons simply require the user to check the checkbox next to the reason with the exception of: Other - Selecting 'Other' will cause the form to refresh with a free text field so that custom reasons can be supplied. All reasons selected will appear on the certificate.

Do you wish to show excipient quantities on the certificate?	Select 'Yes' or 'No'. Selecting yes will cause the system to check the existing ARTG record to see if all excipient ingredients have quantity and unit information. If quantity and unit information is missing from current records a warning will be displayed.
Do you wish to add supplementary information to the formulation?	Select 'Yes' or 'No'. Selecting yes will cause the form to refresh offering the user a list of ingredients against which supplementary information can be supplied. To provide supplementary information, click on the ingredient name. The system will navigate to the supplementary information form where a user can enter supplementary information in a free text field, then click 'Save and close' to be returned to the application form.
Select manufacturer to appear on certificate:	*This field will only appear if the selected sponsor status is (b) or (c), and the user has selected the 'One of the manufacturers recorded against the AUSTL/R selected' option for the 'Display Dosage Form Manufacturer Details?' field.* This field allows for the selection of one manufacturer from all manufacturers listed on the ARTG for the selected AUST L/R. The name and address of the selected manufacturer will appear on the certificate.
Do you wish to show manufacturers on as Schedule 2?	Select 'All', 'Some' or 'None'. Selecting 'Some' will cause the form to refresh with a list of manufacturers. Users can click the 'Don't show' link to have those manufacturers details suppressed from Schedule 2 lists.
Is officially approved information, complete and consonant with the licence, attached?	Select 'Yes', 'Not Provided' or 'No'. This response will appear on the certificate.
Do all manufacturers of this product have a	Select 'Yes' or 'No'. This information will assist TGA's evaluation.

GMP licence and/or a valid overseas Pre-Clearance certificate?	
Certify labels with certificate?	Select 'Yes' if labels are to be included as a schedule. Otherwise, select 'No'.

Electronic Supporting Attachment List:	
Note: Schedules will only be accepted in Hard Copy with original signature. Attachments intended to be part of the certificate must follow Schedule formatting and be signed and dated in original penmanship (that is, not photocopied)	
Attachments:	This is conditionally mandatory depending on if the user has selected to 'Add' an electronic file. One or more electronic files can be attached to the application by clicking 'Add'. An example of an allowable electronic attachment is an application cover letter. To 'Delete' an electronic file select the 'Delete' link under the Action column of Attachments. *Schedules will only be accepted in hard-copy with original signature*

Paper Supporting Document List:	
Note: Schedule will only be accepted in Hard Copy with original signature.	
Document Type:	Select the type of document from the drop-down list.
Description:	Provide a free text description of the document.
Method of Submission:	Select the method via which the document has been (will be sent).
Date Sent:	Select the date on which the document was/will be sent. complete the addition of a paper-supporting document by clicking 'Add' once all the details are completed.

Time Taken	Providing this information is optional. It will be used by TGA to monitor and improve the experience of web users.

6. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
7. 'Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
8. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76

Certificate of Listable Product (CLP) Application

From this form, sponsors can draft and validate an application for a Certificate of Listable Product (CLP).

Creating a CLP Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link, under the Portal select the 'Export Certificates' link
2. The 'Export Certificate' application types will be displayed.
3. Click on the 'Application for Certificate of Listable Product' link
4. The 'Certificate of Listable Product' application form will be displayed in edit mode, ready for information to be entered (see figure 29 below).
5. Complete the application using the information in the following table

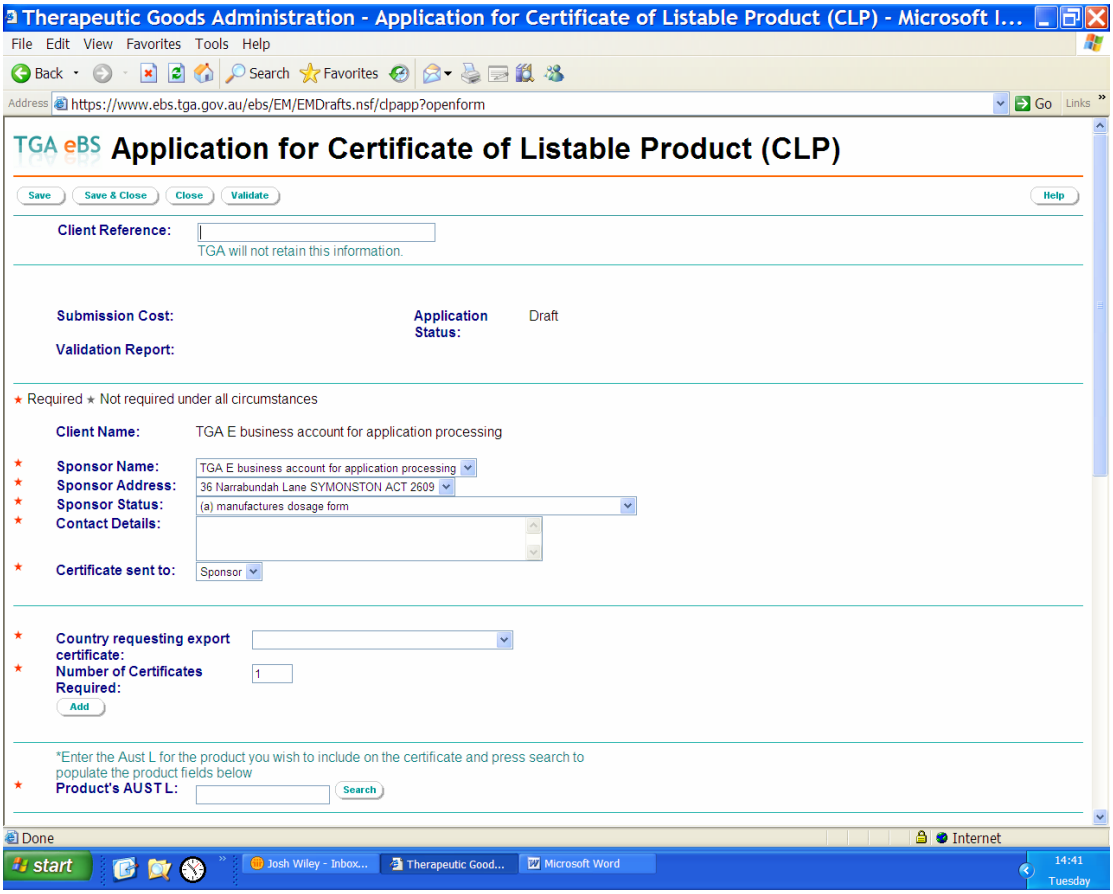

Figure 29. Application form for a CLP

Fields	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Submission cost:	Once the application has been validated, this field displays the submission cost of the application.
Application Status:	This field is populated by the system following validation, depending on the current status of the application.
Validation Report:	On validating the application the system displays a validation report. Messages displayed will indicate any errors with the application. These errors must be fixed before the application can be submitted to the TGA.

Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export- Electronic Lodgement system.
Sponsor Name:	This field is mandatory if the application is being completed by an Agent. Select the appropriate sponsor name from the drop down list.
Sponsor Address:	This field allows for the selection of a street address registered to the sponsor. The selected address is the address that will appear on the certificate.
Sponsor Status:	This field indicates the role of the sponsor in the production of the product. Options are: (a) Manufactures dosage form. (b) Packages, labels and/or releases for supply dosage form manufactured by independent manufacturer. (c) Is involved in none of the above. *If (a) is selected please ensure that the sponsor address selected belongs to a location that is registered and is appropriately licenced for the manufacturing of the chosen product's dosage form/s.*

Display Dosage Form Manufacturer Details?:	*This field will only appear if option (b) or (c) is selected for the sponsor status.* This field offers three choices for the inclusion of the dosage form manufacturer's details: 'Suppress details from certificate': Select this option if you wish to keep the dosage form manufacturer details confidential. 'See Schedule 2 for manufacturing details': Select this option for the words "See Schedule 2" to appear on the certificate. Ensure that you elect to show some or all of the manufacturers listed in the ARTG record for this product on this Schedule. 'One of the manufacturers recorded against the AUSTL/R selected': Select this option to enable one of the manufacturers listed in the ARTG record to be selected in the 'Select manufacturer to appear on certificate' field further down the form.
Contact details:	This field is Mandatory. The name and telephone number of the person who is to be contact for any queries relating to this application are preferred here.
Certificate sent to:	This selects whether the certificate is delivered to the sponsor or a third party. If the Other option is selected the form will refresh with an extra field for the name and address of the recipient

Country requesting export certificate**:**	Select the name of the country requesting an export certificate from the drop-down list, then complete the following field.
Number of Certificates Required:	Please supply the correct number of certificates required by each importing country. Click the 'Add' button to add this request to the form. **Repeat** to add more than one Country to the request. ***Note***: If the 'Add' button is not used, the certificate request for the country will not be added to the CLP.

Product's AUST L	Enter the AUST L of the product the certificate will be created for then click 'Search' to populate other fields. If the AUST L is not valid an error message will appear.
Product name	Populated when a valid AUST R/L is supplied and the user has clicked 'Search'.
Dosage form:	Select the correct dosage form for the product from the drop down list.
Container:	Populated when a valid AUST L is supplied and the user has clicked 'Search'.
Date commenced in the ARTG:	Populated when a valid AUST L is supplied and the user has clicked 'Search'.

Marked for Export Only?	Populated when a valid AUST L is supplied and the user has clicked ‘Search’. Note: This field must be ‘NO’ for a CLP. Yes will mean a CPP is to be issued.
Do you wish to show excipient quantities on the Schedule?	Select ‘Yes’ or ‘No’. Selecting yes will cause the system to check the existing ARTG record to see if all excipient ingredients have quantity and unit information. If Quantity and unit information is missing from current records a warning will be displayed.
Do you wish to add supplementary information to the formulation?	Select ‘Yes’ or ‘No’. Selecting yes will cause the form to refresh offering the user a list of ingredients against which supplementary information can be supplied. To provide supplementary information, click on the ingredient name. The system will navigate to the supplementary information form where a user can enter supplementary information in a free text field, then click ‘Save and close’ to be returned to the application form.
Select manufacturer to appear on certificate:	*This field will only appear if the selected sponsor status is (b) or (c), and the user has selected the ‘One of the manufacturers recorded against the AUSTL/R selected’ option for the ‘Display Dosage Form Manufacturer Details?’ field.* This field allows for the selection of one manufacturer from all manufacturers listed on the ARTG for the selected AUST L/R. The name and address of the selected manufacturer will appear on the certificate.
Do you wish to show manufacturers as Schedule 2?	Select 'All', 'Some' or 'None'. Selecting 'Some' will cause the form to refresh with a list of manufacturers. Users can click the 'Don't show' link to have those manufacturers details suppressed from Schedule 2 lists.
Do all manufacturers of this product have a GMP licence and/or a valid overseas Pre-Clearance certificate?	Select 'Yes' or 'No'. This information will assist TGA's evaluation.
Certify labels with certificate?	Select 'Yes' or 'No'. This information will assist TGA's evaluation

Electronic Supporting Attachment List: ***Note***: Schedule will only be accepted in Hard Copy with original signature. Attachments intended to be part of the certificate must follow Schedule formatting and be signed and dated in original penmanship (that is, not photocopied)	
Attachments:	This is conditionally mandatory depending on if the user has selected to 'Add' an electronic file. One or more electronic files can be attached to the application by clicking 'Add'. An example of an allowable electronic attachment is an application cover letter. To 'Delete' an electronic file select the 'Delete' link under the Action column of Attachments. *Schedules will only be accepted in hard-copy with original signature*

Paper Supporting Document List: ***Note***: Schedule will only be accepted in Hard Copy with original signature.	
Document Type:	Select the type of document from the drop-down list.
Description:	Provide a free text description of the document.
Method of Submission:	Select the method via which the document has been (will be sent).
Date Sent:	Select the date on which the document was/will be sent. Complete the addition of a paper-supporting document by clicking 'Add' once all the details are completed.
Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

6. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
7. Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.

8. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

Certificate of Exempt Product (CEP) Application

From this form, sponsors can draft and validate an application for a Certificate of Exempt Product (CEP).

Creating a CEP Application

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link, under the Portal select the 'Export Certificates' link
2. The 'Export Certificate' application types will be displayed.
3. Click on the 'Application for Certificate of Exempt Product' link
4. The 'Certificate of Exempt Product' application form will be displayed in edit mode, ready for information to be entered (see figure 30 below).
5. Complete the application using the information in the following table

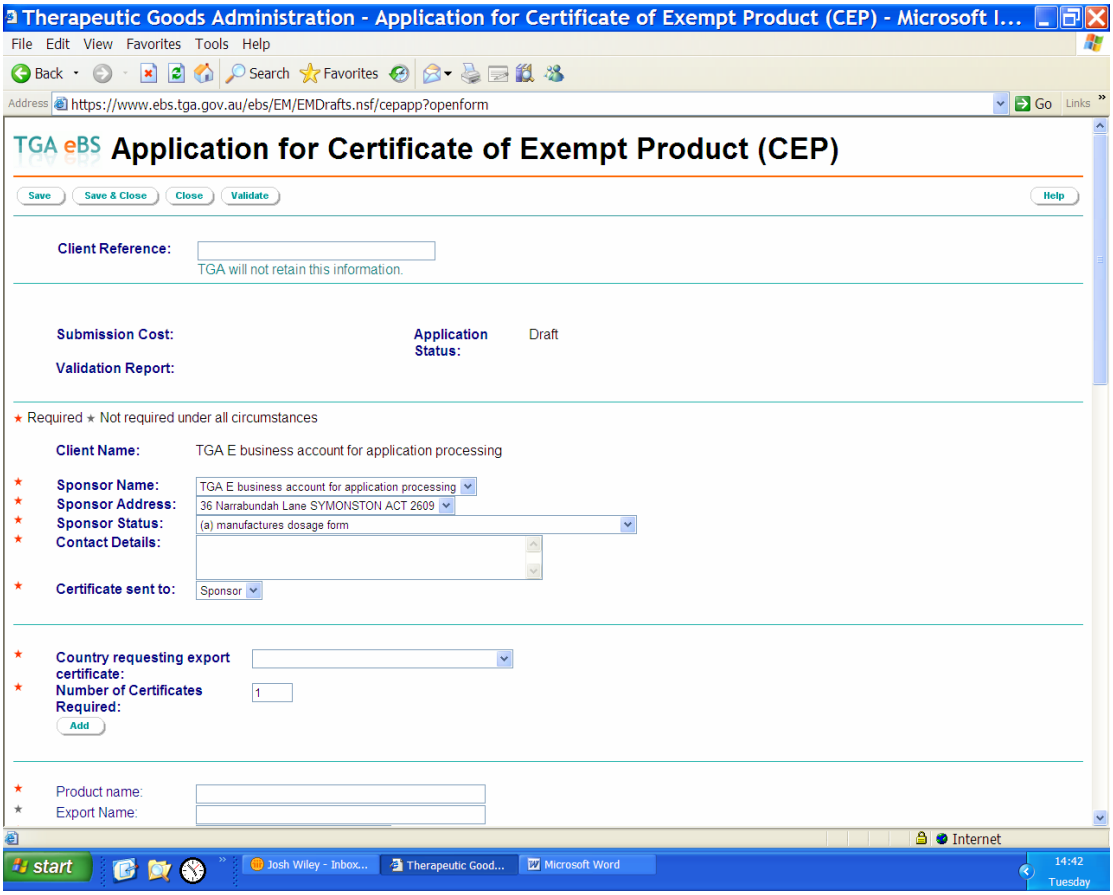

Figure 30. Application for Certificate of Exempt Product (CEP) form

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Field	Description
Client Reference:	This field is not mandatory. Enter a descriptive name useful to you. This reference will be displayed on the main page view to assist in quickly identifying your draft application. TGA will not retain this information.
Submission cost:	Once the application has been validated, this field displays the submission cost of the application.
Application Status:	This field is populated by the system following validation, depending on the current status of the application.
Validation Report:	On validating the application the system displays a validation report. Messages displayed will indicate any errors will the application. These errors must be fixed before the application can be submitted to the TGA.

Client Name:	System inserts client name based on log on ID. Displays your client name based on the logon id used to access the Export Electronic Lodgement - system.
Sponsor Name:	This field is mandatory if the application is being completed by an Agent. Select the appropriate sponsor name from the drop down list.
Sponsor Address:	This field allows for the selection of a street address registered to the sponsor. The selected address is the address that will appear on the certificate.
Sponsor Status:	This field indicates the role of the sponsor in the production of the product. Options are: (a) Manufactures dosage form. (b) Packages, labels and/or releases for supply dosage form manufactured by independent manufacturer. (c) Is involved in none of the above. *If (a) is selected please ensure that the sponsor address selected belongs to a location that is registered and is appropriately licenced for the manufacturing of the chosen product's dosage form/s.*
Display Dosage Form Manufacturer Details?:	*This field will only appear if option (b) or (c) is selected for the sponsor status.* This field offers three choices for the inclusion of the dosage form manufacturer's details: 'Suppress details from certificate': Select this option if you wish to keep the dosage form manufacturer details confidential. 'See Schedule 2 for manufacturing details': Select this option for the words "See Schedule 2" to appear on the

	certificate. Ensure that you elect to show some or all of the manufacturers listed in the ARTG record for this product on this Schedule. Enter the manufacturer's details that you wish to appear on the certificate': Select this option will cause a new text field to be displayed so that the manufacturer's details can be directly entered.

Manufacturer's details to be displayed on certificate:	*This field will only appear if option (b) or (c) is selected for the sponsor status, and the option to 'Enter the manufacturer's details that you wish to appear on the certificate' is selected.* Enter the name and address for the dosage form manufacturer, as it is to appear on the certificate.
Contact Details:	This field is Mandatory. The name and telephone number of the person who is to be contact for any queries relating to this application are preferred here.
Certificate sent to:	This selects whether the certificate is delivered to the sponsor or a third party. If the Other option is selected the form will refresh with an extra field for the name and address of the recipient

Country requesting export certificate**:**	Select the name of the country requesting an export certificate from the drop-down list, then complete the following field.
Number of Certificates Required:	Please supply the correct number of certificates required by each importing country. Click the 'Add' button to add this request to the form. **Repeat** to add more than one Country to the request. ***Note***: If the 'Add' button is not used, the certificate request for the country will not be added to the CEP.

Product name:	Enter the Product Name into the free text field.
Export name:	This is a free text field for users to enter the export name of the product. If an export name is selected. The export name will appear on the certificate in place of the product name.
Dosage form:	Select the correct dosage form for the product from the drop down list.

Is this product on the market in Australia?	If 'Yes' is selected for this question, there is no requirement to supply a reason (as listed below), however if the product is not on the market in Australia, 'No' must be selected and then one or more reasons why must also be selected.

Reasons the product is not on the market in Australia:	Select one or more reasons why the product is not on the market in Australia. Most reasons simply require the user to check the checkbox next to the reason with the exception of; This product has the same formulation as another product on the Australia market which is supplied in a different container or packaging. If selected, the form will refresh to allow for the selection of an existing ARTG entry. This product is approved for supply in the following markets (list countries below) - If selected one or more countries will need to be selected from the list supplied. To select multiple countries, hold the Ctrl key whilst clicking on the name of each country to be included. Other - Selecting 'Other' will cause the form to refresh with a free text field so that custom reasons can be supplied. All reasons selected will appear on the certificate.
Ingredient:	Click ‘Add’ to search for and select one or more ingredients for the product. For details on completing the Ingredient subform, refer to Page 43.
Manufacturer:	Click ‘Add’ to search for and select one or more manufacturers for the product. For details on completing the Manufacturer subform, refer to Page 47.

Electronic Supporting Attachment List: ***Note***: Schedule will only be accepted in Hard Copy with original signature. Attachments intended to be part of the certificate must follow Schedule formatting and be signed and dated in original penmanship (that is, not photocopied)	
Attachments:	This is conditionally mandatory depending on if the user has selected to ‘Add’ an electronic file. One or more electronic files can be attached to the application by clicking ‘Add’. An example of an allowable electronic attachment is an application cover letter. To ‘Delete’ an electronic file select the ‘Delete’ link under the Action column of Attachments. *Schedules will only be accepted in hard-copy with original signature*

Paper Supporting Document List: ***Note***: Schedule will only be accepted in Hard Copy with original signature.	
Document Type:	Select the type of document from the drop-down list.
Description:	Provide a free text description of the document.
Method of Submission:	Select the method via which the document has been (will be sent).
Date Sent:	Select the date on which the document was/will be sent. Complete the addition of a paper-supporting document by clicking ‘Add’ once all the details are completed.

Time Taken	An optional field. Data entered to only be used by TGA to monitor and improve the experience of web users.

6. Validation of the application. Refer to 'Validating an Application' on Page 74 for details.
7. Save and Close' the application. The application will now be available from the 'View Drafts" option underneath the Portal. Refer to Page 75 for details on viewing Draft Applications.
8. If the application has the status of 'Passed Validation' it can now be submitted to the TGA. For details on Submitting applications, please refer to Page 76.

Validating an Application

What Happens During the Validation of an Application

Validation is a necessary step for all applications. This step is necessary to ensure that your application complies with the rules and legislation that apply to each type of application, and that all mandatory fields are satisfactorily completed.

How to validate an application

1. To validate an application select the 'Validate' button (see picture below) at the top or bottom of the application.

2. Validation will check the draft application against a set of Rules maintained by TGA.
3. A Validation Report will be displayed on the application, under the heading 'Validation Report', indicating any contraindications to the validation rules. These errors must be rectified in order to proceed.

The validation occurs in a multi-step process, during which the validation that is conducted becomes more rigorous with each step. An application that fails validation during an early step will only report the errors that caused that failure. This may lead to a number of errors initially not being reported. Once all errors that have been reported are fixed, then validation should be re-conducted (by clicking on the Validate button again), and if any further errors are identified, they should be fixed. Please be aware that it may take several attempts to successfully validate an application.

Example: Joe Bloggs, of Bloggs & Sons Pharmaceuticals is submitting an S26 General Listing Application. Joe has completed most of his application details, except that he has forgotten to complete the container type and attached documents list. Joe clicks on the validate button and his application fails validation. The validation messages indicate that Joe's application is missing mandatory information. Because this missing information has caused validation to fail, validation checks for ingredient quantities, manufacturing steps and other detailed information were not conducted, and therefore not reported.

Joe corrects his application by adding the supporting documents and specifying the container type. He clicks the validate button again. Validation will pass with respect to the checks for mandatory information, but may still fail if there are other problems in Joe's application such as component quantities being of a greater mass than the parent ingredient.

4. Once the application has successfully validated the 'Validation Report' will indicate the application has 'Passed Validation'
5. Save and Close the application.
6. The application can now be submitted to the TGA using the process shown on Page 77.

Existing Drafts

Existing Draft Applications and Certificates

Where are Existing Drafts Located

All existing drafts for not only EEL, but all of TGA's other electronic application lodgement facilities can be found in the main Drafts view which is accessed underneath the Portal (see Figure 31 below)
Having clicked on the Portal, users click on the View Drafts link. Further filtering of desired draft applications can then be made using dropdown lists located at the end of the 'Approval Area' and 'Sponsor' fields.

1.

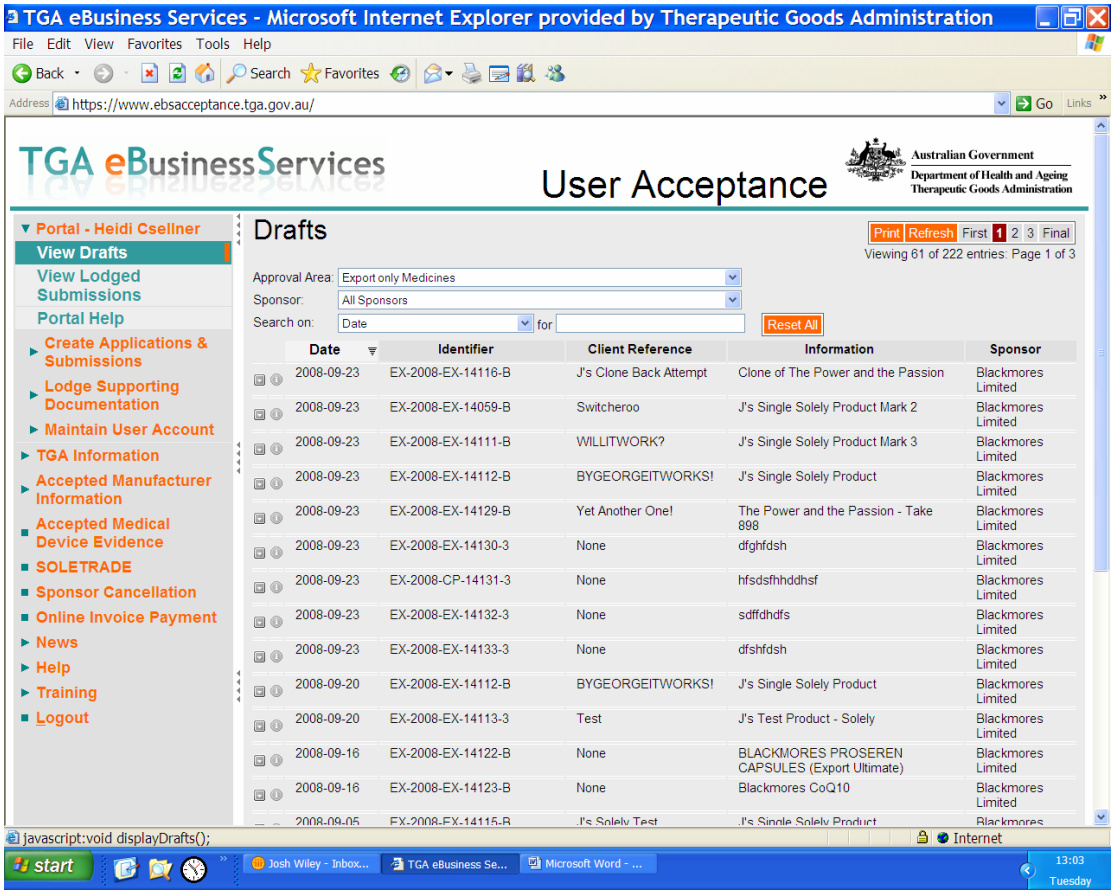
TGA eBusiness Services - Microsoft Internet Explorer provided by Therapeutic Goods Administration
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/
Go Links
TGA eBusinessServices
User Acceptance
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
Portal - Heidi Cseilner
View Drafts
View Lodged Submissions
Portal Help
Create Applications & Submissions
Lodge Supporting Documentation
Maintain User Account
TGA Information
Accepted Manufacturer Information
Accepted Medical Device Evidence
SOLETRADE
Sponsor Cancellation
Online Invoice Payment
News
Help
Training
Logout
Drafts
Print Refresh First 1 2 3 Final
Viewing 61 of 222 entries: Page 1 of 3
Approval Area: Export only Medicines
Sponsor: All Sponsors
Search on: Date for
Reset All
Date Identifier Client Reference Information Sponsor
2008-09-23 EX-2008-EX-14116-B J's Clone Back Attempt Clone of The Power and the Passion Blackmores Limited
2008-09-23 EX-2008-EX-14059-B Switcheroo J's Single Solely Product Mark 2 Blackmores Limited
2008-09-23 EX-2008-EX-14111-B WILLITWORK? J's Single Solely Product Mark 3 Blackmores Limited
2008-09-23 EX-2008-EX-14112-B BYGEORGEITWORKS! J's Single Solely Product Blackmores Limited
2008-09-23 EX-2008-EX-14129-B Yet Another One! The Power and the Passion - Take 898 Blackmores Limited
2008-09-23 EX-2008-EX-14130-3 None dfghfdsh Blackmores Limited
2008-09-23 EX-2008-CP-14131-3 None hfsdsfhhddhsf Blackmores Limited
2008-09-23 EX-2008-EX-14132-3 None sdffdhdfs Blackmores Limited
2008-09-23 EX-2008-EX-14133-3 None dfshfdsh Blackmores Limited
2008-09-20 EX-2008-EX-14112-B BYGEORGEITWORKS! J's Single Solely Product Blackmores Limited
2008-09-20 EX-2008-EX-14113-3 Test J's Test Product - Solely Blackmores Limited
2008-09-16 EX-2008-EX-14122-B None BLACKMORES PROSEREN CAPSULES (Export Ultimate) Blackmores Limited
2008-09-16 EX-2008-EX-14123-B None Blackmores CoQ10 Blackmores Limited
javascript:void displayDrafts();
Internet
start
Josh Wiley - Inbox...
TGA eBusiness Se...
Microsoft Word - ...
13:03
Tuesday

Figure 31. Drafts view for all application types (Export Only Medicines filter shown here displays only Export Only draft applications)

Making a Submission

Making a Submission

The Make Submission page is used to select one or more validated applications to be submitted to TGA for processing and listing on the ARTG. Submissions may be made for the following types of applications:

1. S.26 – Export Only Applications
2. S.26a – Solely for Export Applications
3. Export Certificates

How to make a submission

1. From the 'Export Only Medicine' link underneath the 'Create Applications & Submissions' link, under the Portal select the 'Submission' link.
2. The different types of Export Only applications will be displayed. Select the appropriate application type eg Certificates. .
3. The 'Make Submission' page is displayed as shown in Figure 31 below.

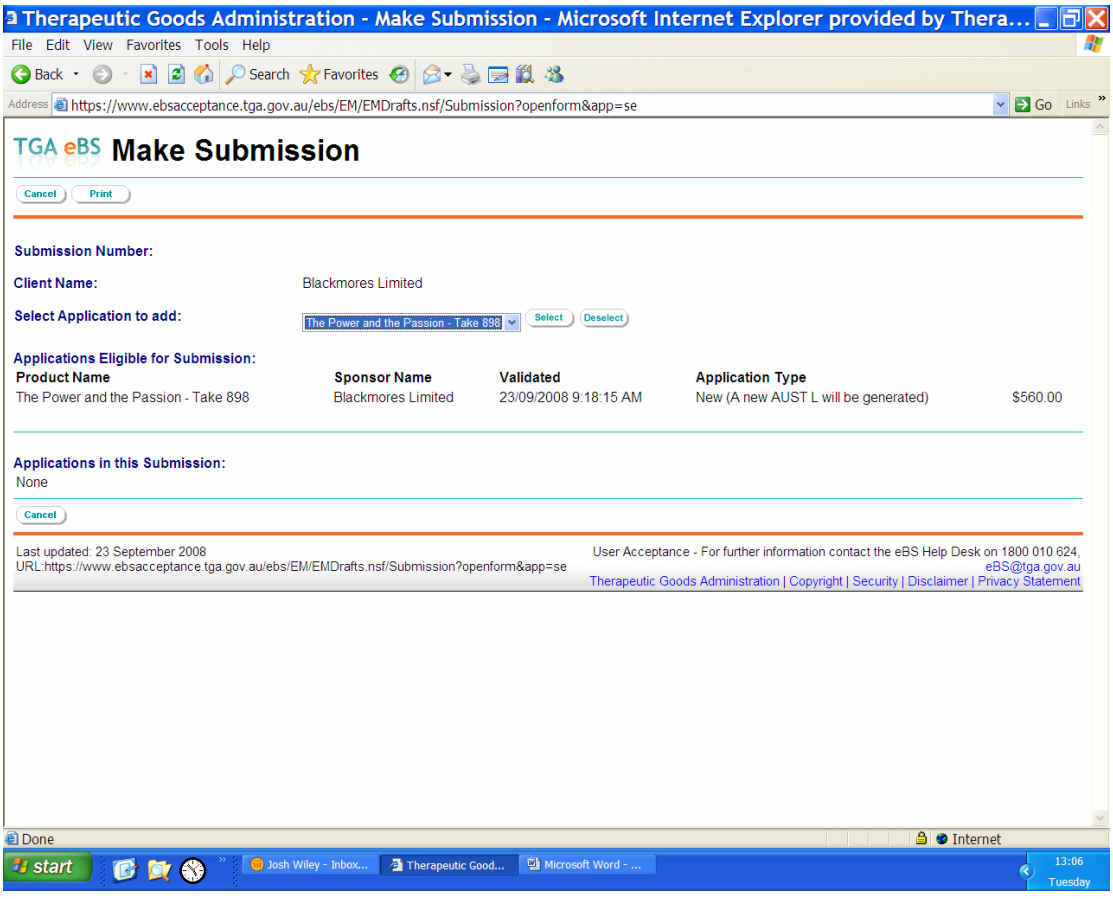
Therapeutic Goods Administration - Make Submission - Microsoft Internet Explorer provided by Thera...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/Submission?openform&app=se
Go Links
TGA eBS Make Submission
Cancel Print
Submission Number:
Client Name: Blackmores Limited
Select Application to add: The Power and the Passion - Take 898 Select Deselect
Applications Eligible for Submission:
Product Name Sponsor Name Validated Application Type
The Power and the Passion - Take 898 Blackmores Limited 23/09/2008 9:18:15 AM New (A new AUST L will be generated) $560.00
Applications in this Submission:
None
Cancel
Last updated: 23 September 2008
URL:https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/Submission?openform&app=se
User Acceptance - For further information contact the eBS Help Desk on 1800 010 624, eBS@tga.gov.au
Therapeutic Goods Administration | Copyright | Security | Disclaimer | Privacy Statement
Done
Internet
start
Josh Wiley - Inbox...
Therapeutic Good...
Microsoft Word - ...
13:06
Tuesday

Figure 31. Make Submission Page

4. ‘Select the application to add’ to the submission using the drop-down list.
   Note: Only those applications that have passed validation will be available in the list. If the application is not in the list check the Existing Drafts folder and ensure the application has passed validation.
5. Single click the ‘Select’ button to submit the selected applications. A message will be displayed requiring that the Statutory Declaration be read and the ‘Agree’ or Disagree’ button must be selected. Select ‘OK’, The Statutory Declaration will be displayed.
6. Read the Declaration and select the appropriate button at the bottom of the form (Agree or Disagree).
7. The ‘Make Submission’ page will be displayed with the selected application in the ‘Applications in this Submission’ table at the bottom of the form.
8. If more than one application is to be submitted repeat steps 4-7 above.
9. Once all applications to be submitted are showing in the table, select the ‘Submit’ button.
10. The ‘Checklist’ page will be displayed (See figure 32 below).

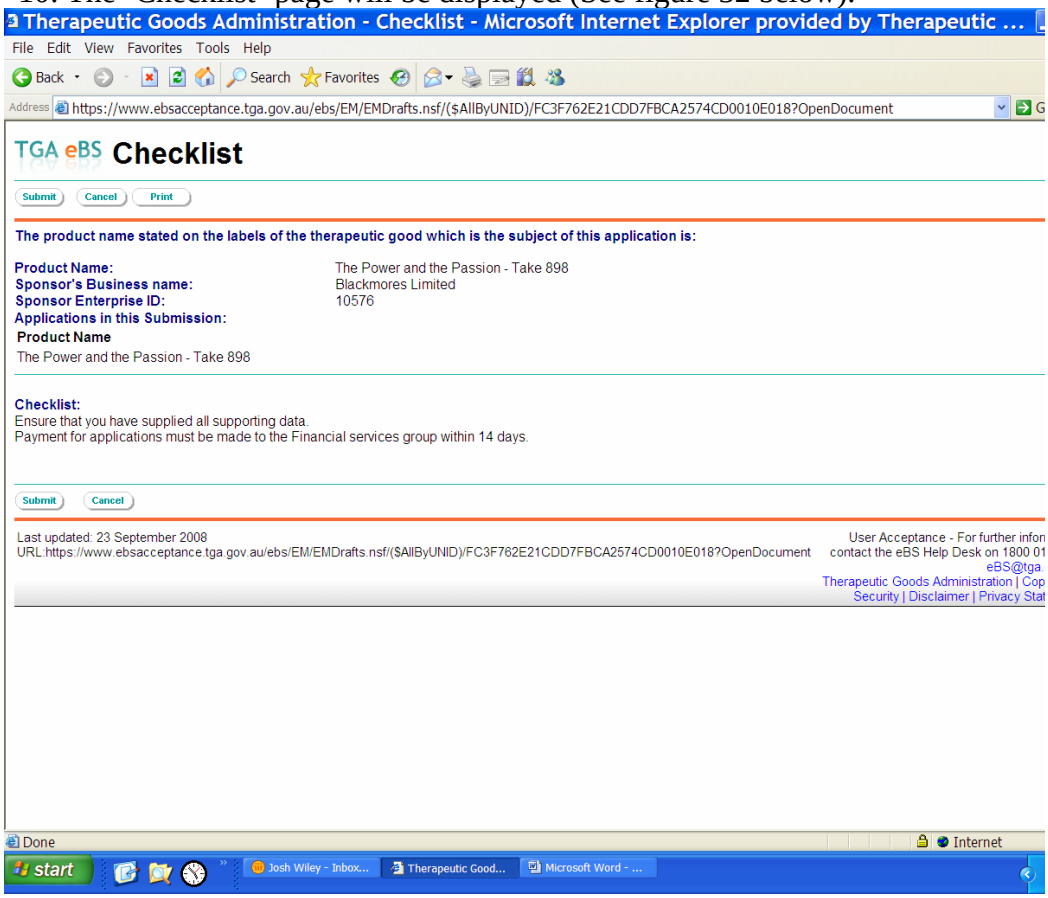
Therapeutic Goods Administration - Checklist - Microsoft Internet Explorer provided by Therapeutic ...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/($AllByUNID)/FC3F762E21CDD7FBCA2574CD0010E018?OpenDocument
TGA eBS Checklist
Submit Cancel Print
The product name stated on the labels of the therapeutic good which is the subject of this application is:
Product Name: The Power and the Passion - Take 898
Sponsor's Business name: Blackmores Limited
Sponsor Enterprise ID: 10576
Applications in this Submission:
Product Name
The Power and the Passion - Take 898
Checklist:
Ensure that you have supplied all supporting data.
Payment for applications must be made to the Financial services group within 14 days.
Submit Cancel
Last updated: 23 September 2008
URL:https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/($AllByUNID)/FC3F762E21CDD7FBCA2574CD0010E018?OpenDocument
User Acceptance - For further infon
contact the eBS Help Desk on 1800 01
eBS@tga.
Therapeutic Goods Administration | Cop
Security | Disclaimer | Privacy Stat
Done
Internet
start
Josh Wiley - Inbox...
Therapeutic Good...
Microsoft Word - ...

Figure 32. Submission Check List

11. Select the ‘Submit’ button.
12. The Payment Lodgement’ page will be displayed (See figure 33 below).

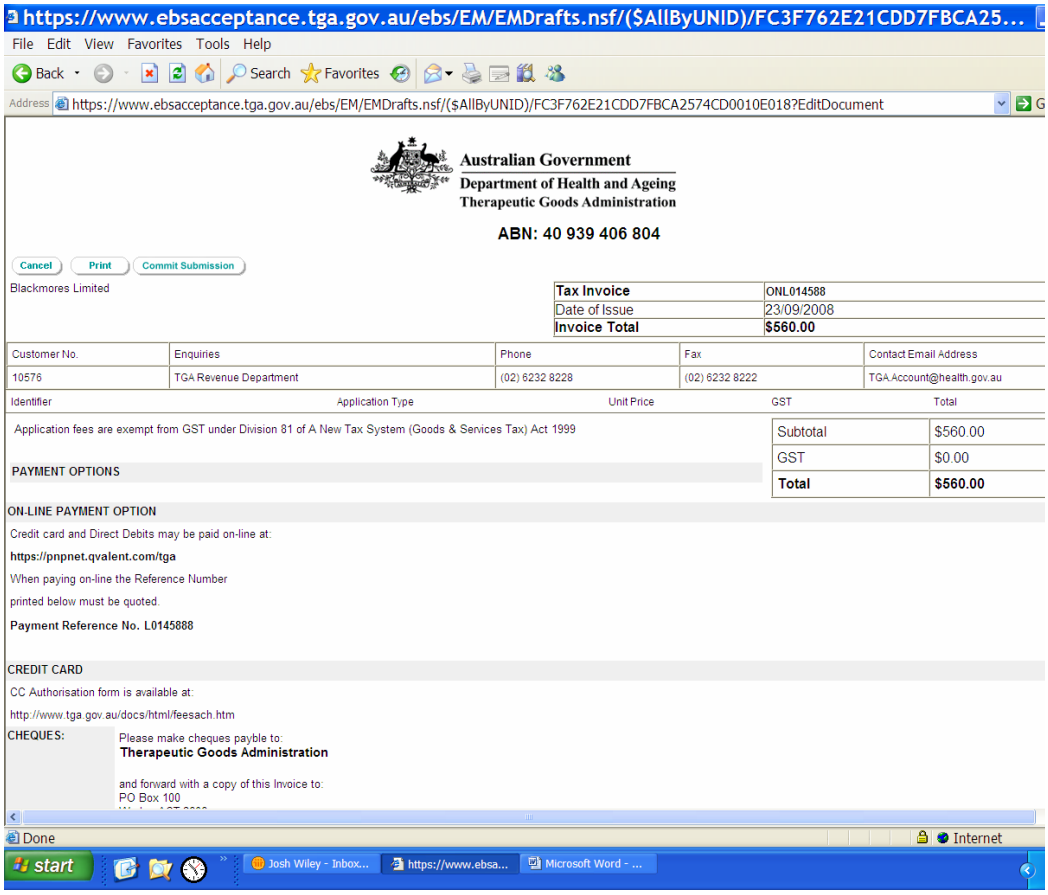
https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/($AllByUNID)/FC3F762E21CDD7FBCA25...
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.ebsacceptance.tga.gov.au/ebs/EM/EMDrafts.nsf/($AllByUNID)/FC3F762E21CDD7FBCA2574CD0010E018?EditDocument
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
ABN: 40 939 406 804
Cancel Print Commit Submission
Blackmores Limited
Tax Invoice ONL014588
Date of Issue 23/09/2008
Invoice Total $560.00
Customer No. Enquiries Phone Fax Contact Email Address
10576 TGA Revenue Department (02) 6232 8228 (02) 6232 8222 TGA.Account@health.gov.au
Identifier Application Type Unit Price GST Total
Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999
Subtotal $560.00
GST $0.00
Total $560.00
PAYMENT OPTIONS
ON-LINE PAYMENT OPTION
Credit card and Direct Debits may be paid on-line at:
https://pnpnet.qvalent.com/tga
When paying on-line the Reference Number
printed below must be quoted.
Payment Reference No. L0145888
CREDIT CARD
CC Authorisation form is available at:
http://www.tga.gov.au/docs/html/feesach.htm
CHEQUES:
Please make cheques payble to:
Therapeutic Goods Administration
and forward with a copy of this Invoice to:
PO Box 100
Done
Internet
start
Josh Wiley - Inbox...
https://www.ebsa...
Microsoft Word - ...

Figure 33. Payment Lodgement form

13. PRINT the Payment Lodgement form, complete the details and send it to the TGA or use the Credit Card link to pay for the submission online.
    ***Note*: It is essential that users Print the payment form at this stage as once the application is committed, the payment form can not be retrieved.**
14. Select the 'Commit Submission' button.
15. The applications will then be submitted to the TGA for processing.

Note: The application will now be visible from the 'Submitted Applications' view.

Submitted Applications

Viewing Submitted Applications

This screen provides a list of all submitted applications that a sponsor has permission to access (generally only the applications that a sponsor themselves has drafted). The user has the ability to track the progress of submitted applications or delete any unwanted drafts.
Submitted applications may be viewed by clicking on the 'View Lodged Submissions' link accessed underneath the Portal (see Figure 34 below)
Further filtering of desired draft applications can then be made using dropdown lists located at the end of the 'Approval Area' and 'Sponsor' fields.

1.

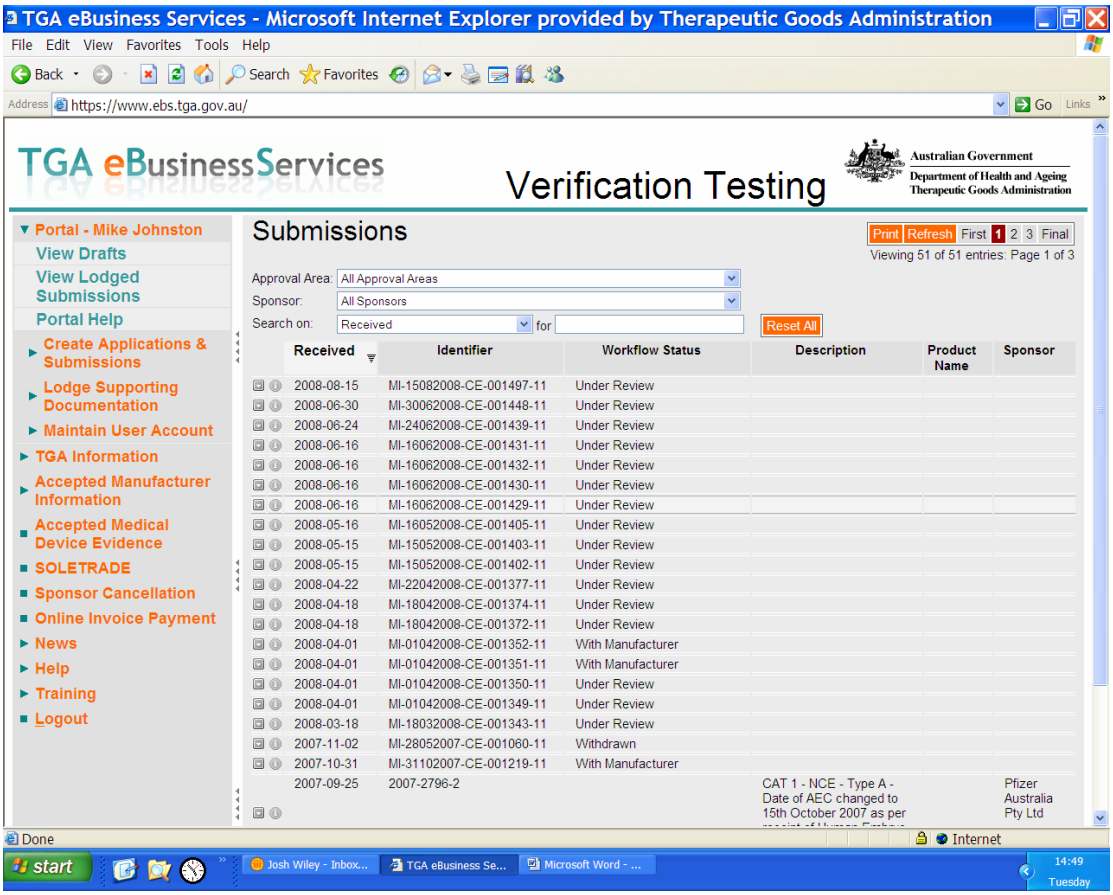

Figure 34. Submitted Applications view (View is showing 'All Approval Areas' filter

Withdrawing an Application

Once an application has been submitted to the TGA, it can be withdrawn at any point up until it is approved and written to the ARTG. If you wish to withdraw an applications:

1. Click on the 'View Lodged Submissions' as shown in Figure 34 above.
2. Click on the Arrow icon in front of the date received to reveal option to 'Delete' the application.

Australian Register of Therapeutic Goods (ARTG) Records

ARTG Records

The ARTG holds records of all Therapeutic Goods that have been approved for distribution in Australia and for export. The Web view of the ARTG only shows current entries and does not include entries that have been cancelled from the ARTG.

The system also provides on-line access via the Internet for members of the public to appropriately restricted subsets of the information on the ARTG (i.e. legally appropriate information).

Access

- A Sponsor who has been provided with a valid logon to TGA's SIME Web Site can read information concerning entries they have listed/registered on the ARTG and print out an ARTG Certificate for their own products.
- An Agent who has been provided with a valid logon to TGA's SIME Web Site can read information concerning entries for all Sponsors they are authorised to represent.
- Members of the public have read access to query the ARTG for specific products, or ingredients that may be contained in a product (no logon required).

Viewing ARTG Records

The Sponsor of Export medicines that are current and recorded in the ARTG database for which the organisation is sponsor or their agent can view their entries.

To View ARTG Records see figure 35 below:

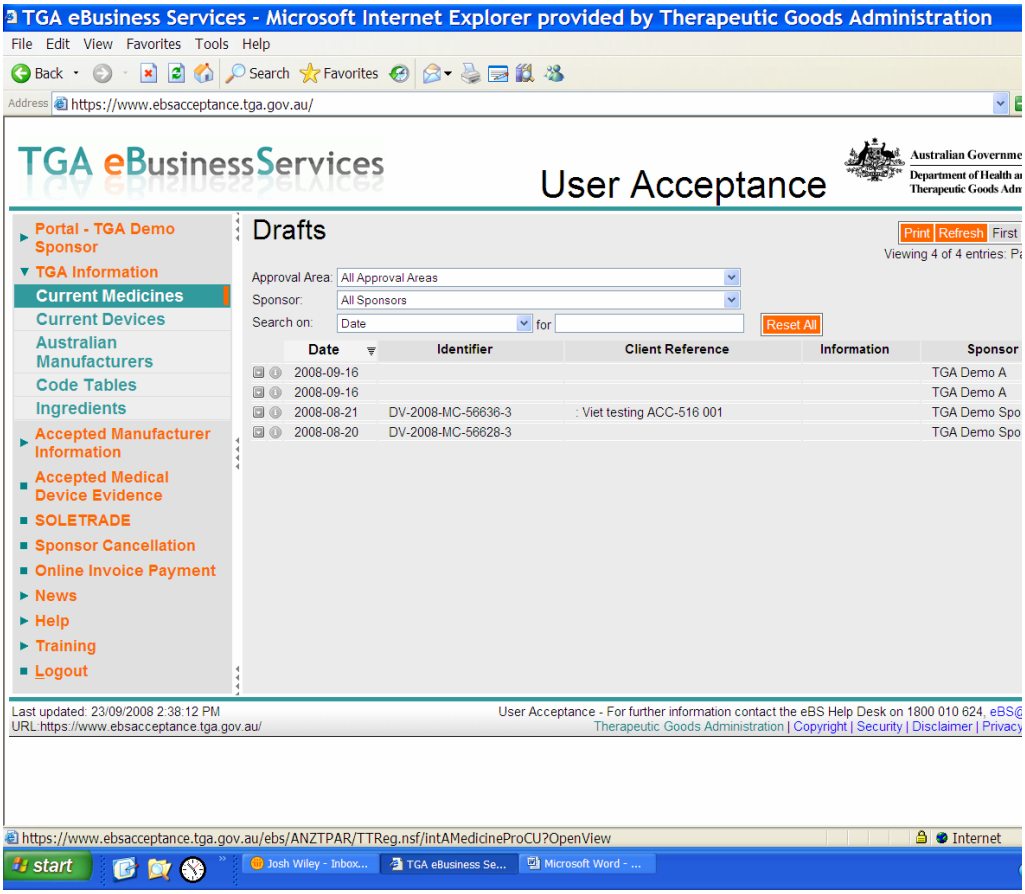

Figure 35. Accessing ARTG Information from the eBS Home Page

1. From the E Business Home Page select the ‘TGA Information’ link
2. To view Medicines on the ARTG, select the ‘Current Medicines’ link. An example is provided below.

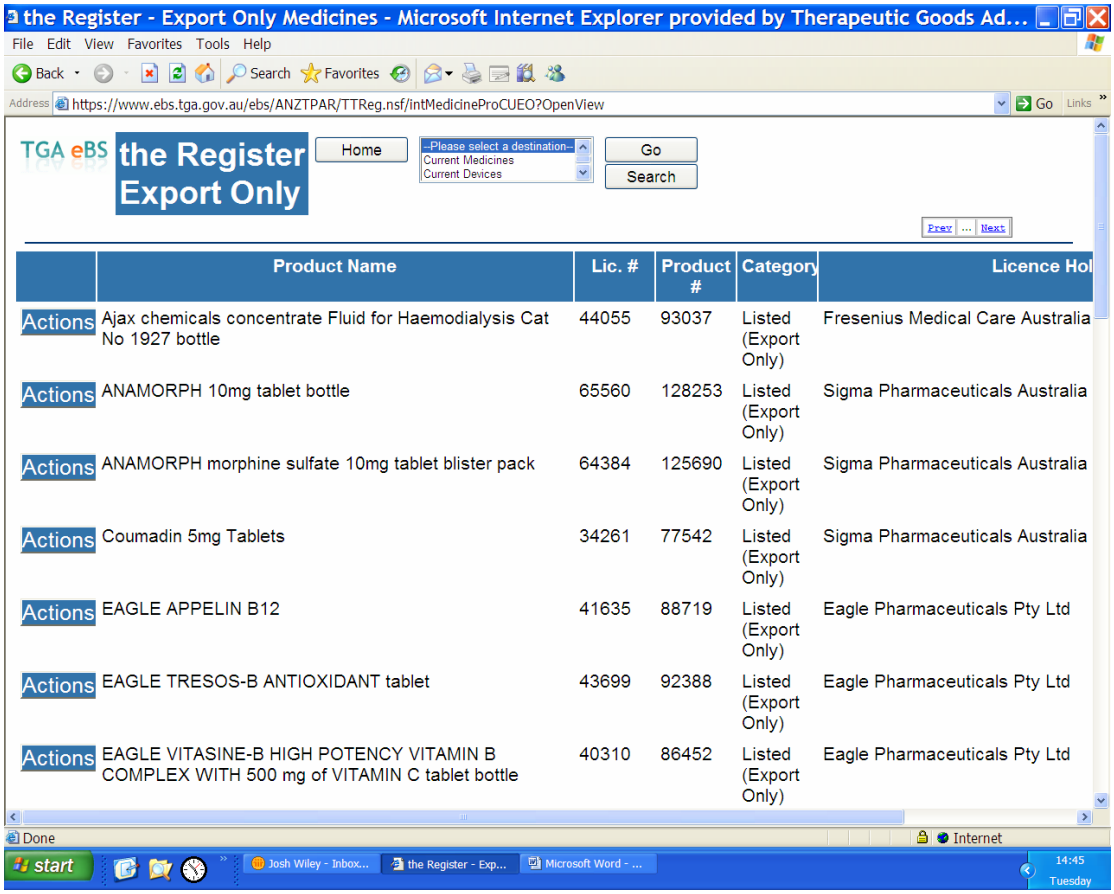
the Register - Export Only Medicines - Microsoft Internet Explorer provided by Therapeutic Goods Ad...
File Edit View Favorites Tools Help
Back Search Favorites
https://www.ebs.tga.gov.au/ebs/ANZTPAR/TTReg.nsf/intMedicineProCUEO?OpenView
TGA eBS
the Register Export Only
Home
--Please select a destination--
Current Medicines
Current Devices
Go
Search
Prev ... Next
Product Name
Lic. #
Product #
Category
Licence Hol
Actions Ajax chemicals concentrate Fluid for Haemodialysis Cat No 1927 bottle 44055 93037 Listed (Export Only) Fresenius Medical Care Australia
Actions ANAMORPH 10mg tablet bottle 65560 128253 Listed (Export Only) Sigma Pharmaceuticals Australia
Actions ANAMORPH morphine sulfate 10mg tablet blister pack 64384 125690 Listed (Export Only) Sigma Pharmaceuticals Australia
Actions Coumadin 5mg Tablets 34261 77542 Listed (Export Only) Sigma Pharmaceuticals Australia
Actions EAGLE APPELIN B12 41635 88719 Listed (Export Only) Eagle Pharmaceuticals Pty Ltd
Actions EAGLE TRESOS-B ANTIOXIDANT tablet 43699 92388 Listed (Export Only) Eagle Pharmaceuticals Pty Ltd
Actions EAGLE VITASINE-B HIGH POTENCY VITAMIN B COMPLEX WITH 500 mg of VITAMIN C tablet bottle 40310 86452 Listed (Export Only) Eagle Pharmaceuticals Pty Ltd
Done
Internet
start
Josh Wiley - Inbox...
the Register - Exp...
Microsoft Word - ...
14:45
Tuesday

Figure 36. ARTG Records view of Export Only Medicines

1.

Searching ARTG Records

The ARTG can be searched using a variety of filters eg by medicines, devices, export only products
To search for records on the ARTG:

1. Click on the 'Search' button on the Button Bar on the List of Entries screen.
2. The Full Text Search screen will be displayed.
3. Enter a word (or words) to search for, in the search field
4. Select the number of results to be returned (click on the downwards facing arrow to get a list to choose from)
5. Select sort and word match options, as required
6. Click on the 'Search' button.

Printing ARTG Certificates

To print an ARTG Certificate of the product's details on the ARTG, click on the blue 'Actions' button to the left of the ARTG product listing name. The option of 'Create ARTG Certificate' appears. Click on this to obtain certificate.

Other Features

Export News

'Export News' is available from the "News" link on the eBusiness home page.

The Export News link displays the latest news, information and status of the Export Medicine system.

This screen will keep users informed of any changes or problems with the Export system on a daily basis.

Figure 4. Export News Page from eBusiness Home Page